



Health Service
LOS ANGELES COUNTY

September 17, 2013

ADOPTED

BOARD OF SUPERVISORS
COUNTY OF LOS ANGELES

**Los Angeles County
Board of Supervisors**

Gloria Molina
First District

Mark Ridley-Thomas
Second District

Zev Yaroslavsky
Third District

Don Knabe
Fourth District

Michael D. Antonovich
Fifth District

Mitchell H. Katz, M.D.
Director

Hal F. Yee, Jr., M.D., Ph.D.
Chief Medical Officer

Christina R. Ghaly, M.D.
Deputy Director, Strategic Planning

313 N. Figueroa Street, Suite 912
Los Angeles, CA 90012

Tel: (213) 240-8101
Fax: (213) 481-0503

www.dhs.lacounty.gov

To ensure access to high-quality, patient-centered, cost-effective health care to Los Angeles County residents through direct services at DHS facilities and through collaboration with community and university partners

The Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, CA 90012

Dear Supervisors:

**AUTHORIZATION TO ACCEPT AN AWARD AND FUTURE AWARDS
FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
TO PROVIDE HANSEN'S DISEASE OUTPATIENT MEDICAL
SERVICES AT LAC+USC MEDICAL CENTER
(FIRST SUPERVISORIAL DISTRICT)
(3 VOTES)**

SUBJECT

Authorization for the Department of Health Services to accept an Award and future awards from the Department of Health and Human Services' National Hansen's Disease Programs for the continued provision of outpatient medical services to patients with Hansen's disease at LAC+USC Medical Center.

IT IS RECOMMENDED THAT THE BOARD:

1. Authorize and instruct the Director of Health Services (Director), or his designee, to accept and sign an Award Number HSH258201300015C (Award), substantially similar to Exhibit I, from the U.S. Department of Health and Human Services Health Resources and Services Administration's National Hansen's Disease Program (herein "HRSA") to receive: i) \$89,738.88 for provision of outpatient medical services to Hansen's disease patients at LAC+USC Medical Center (LAC+USC MC) effective upon Board approval through December 31, 2013; and ii) \$336,520.80 annually for each annual option exercised by HRSA to extend the Award, for an estimated total award of \$1,435,822.08 for the period through December 31, 2017.
2. Delegate authority to the Director, or his designee, to accept and sign any HRSA documents needed to effectuate the options to extend the term of the Award or to make non-substantive

23 September 24, 2013

Sachi A. Hamai
SACHI A. HAMAI
EXECUTIVE OFFICER



www.dhs.lacounty.gov

changes to the Award, subject to review and approval by County Counsel.

3. Delegate authority to the Director, or his designee, to accept and sign future awards from HRSA for the continued treatment of Hansen's disease patients, as well as any documents to extend or otherwise non-substantively change such awards, subject to review and approval by County Counsel, and with notice to the Board and Chief Executive Office (CEO).

PURPOSE/JUSTIFICATION OF RECOMMENDED ACTIONS

Approval of the recommended actions will allow the Department of Health Services to continue to receive funding from HRSA, helping defray approximately 67 percent of the cost of providing Hansen's disease diagnosis, outpatient treatment, case management, follow-up of persons diagnosed with Hansen's disease, and screening of any person who has lived in the same household with a new Hansen's disease patient in the three year period prior to the diagnosis and the beginning of treatment. Hansen's disease is more commonly known as leprosy.

Care for patients with Hansen's disease has been provided at LAC+USC MC since July 1973 and since 1981, the federal government has been providing funding for the Hansen's disease outpatient medical services program.

Implementation of Strategic Plan Goals

The recommended actions support Goal 1, Operational Effectiveness, and Goal 2, Fiscal Sustainability, of the County's Strategic Plan.

FISCAL IMPACT/FINANCING

The total award is in the amount of \$1,435,822.08 effective upon Board approval through December 31, 2017. The annual program cost is \$501,619.80, funded by \$336,520.80 in HRSA funds, estimated Medi-Cal Revenue of \$39,535 and net County cost of \$125,564. Attachment A provides detail of the award. Funding is included in the Fiscal Year 2013-14 Adopted Budget and will be requested in future fiscal years.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS

The federal Hansen's disease program is authorized by Public Law 99-117, Section 2. (a), Section 320 and is administered by the Department of Health and Human Services in accord with their regulations. When the federal government closed its public health hospitals in 1981, a contract care program was developed to provide services in communities where the majority of people with Hansen's disease were identified as residing. As a result, outpatient Hansen's disease clinics formed in California, Georgia, Florida, Illinois, Massachusetts, New York, Puerto Rico, Texas and Washington. Since

this time, LAC+USC MC is designated as a regional center with a catchment area that includes the following counties: Kern, Orange, San Luis Obispo, Santa Barbara, San Bernardino, Tulare and Ventura. The two other California regional centers are in San Diego and San Francisco.

Since 1981, the Board has approved acceptance of HRSA awards for the continued provision of this program. The most recent approval was on March 6, 2007, which extended the provision of services through December 31, 2009. While funds were received for the provision of uninterrupted services for Hansen's disease for the period January 1, 2010 through September 24, 2013, the funds were accepted by LAC+USC MC without approval of the Board. LAC+USC MC staff mistakenly accepted the award without following the Board's contract acceptance guidelines. Steps have been taken to remind LAC+USC MC staff regarding the bodies, and representatives thereof, that are legally authorized to contract on behalf of the County of Los Angeles (including those which bring revenue to the County).

Services have continued to be provided uninterrupted and the federal government has been providing funding to support the program throughout this time period.

Board approval of the recommended actions will authorize the acceptance of the award from HRSA to help support the continued provision of Hansen's disease outpatient medical services at LAC+USC MC for individuals in the Los Angeles catchment area with the central goal of preventing disability through early diagnosis and treatment.

County Counsel has approved the attached Award, Exhibit I, as to form.

CONTRACTING PROCESS

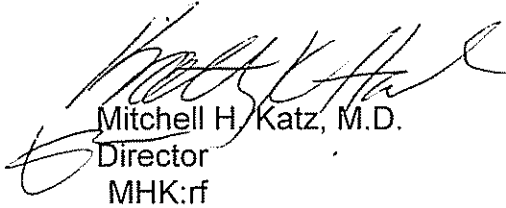
The County receives funds from HRSA to provide medical care to Hansen's disease patients, therefore the County's contracting process is not applicable.

IMPACT ON CURRENT SERVICES (OR PROJECTS):

Approval of the recommended actions will allow LAC+USC MC to continue receiving funds to provide vital outpatient medical services to Hansen's disease patients to prevent disability through early diagnosis and treatment.

The Honorable Board of Supervisors
September 17, 2013
Page 4

Respectfully submitted,



Mitchell H. Katz, M.D.
Director
MHK:rf

Enclosures (2)

c: Chief Executive Office
County Counsel
Executive Office, Board of Supervisors

ATTACHMENT A

**CONTRACT AWARD WITH THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES TO PROVIDE HANSEN'S DISEASE OUTPATIENT MEDICAL SERVICES
AT LAC+USC MEDICAL CENTER FOR THE PERIOD**

EFFECTIVE UPON BOARD APPROVAL* – DECEMBER 31, 2017

PERIOD	DATE	AMOUNT
Base	Effective upon Board approval - December 31, 2013	\$ 89,738.88
Option Period One	January 1, 2014 - December 31, 2014	\$336,520.80
Option Period Two	January 1, 2015 - December 31, 2015	\$336,520.80
Option Period Three	January 1, 2016 - December 31, 2016	\$336,520.80
Option Period Four	January 1, 2017 - December 31, 2017	\$336,520.80
	TOTAL -	\$1,435,822.08

*Board of Supervisors approval is anticipated to be on September 17, 2013.

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING		PAGE OF PAGES 1 43	
2. CONTRACT (Proc. Inst. Ident.) NO. HSH258201300015C				3. EFFECTIVE DATE 09/25/2013		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. HRS115260	
5. ISSUED BY HRSA/OAMP/NHDP Office of Acquisition Management and Policy National Hansen's Disease Program Baton Rouge LA 70816		CODE NHDP		6. ADMINISTERED BY (If other than Item 5)		CODE	
7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, Country, State and ZIP Code) LOS ANGELES, COUNTY OF 136990 LOS ANGELES COUNTY-U S C MEDICAL CE 1200 N STATE ST RM 1900 LOS ANGELES CA 900331029				8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)			
				9. DISCOUNT FOR PROMPT PAYMENT			
				10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN			
CODE 136990		FACILITY CODE		ITEM			
11. SHIP TO/MARK FOR National Hansen's Disease Program A 1770 Physicians Park Drive Baton Rouge LA 70816		CODE NHDP/ADM/CONTRACTS		12. PAYMENT WILL BE MADE BY NHDP/FMO 1770 Physicians Park Drive Financial Management Office Baton Rouge LA 70816		CODE NHDP/FMO	
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304 (c) () <input type="checkbox"/> 41 U.S.C. 253 (c) ()				14. ACCOUNTING AND APPROPRIATION DATA .. 2013.3280075.25627			
15A. ITEM NO	15B. SUPPLIES/SERVICES			15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
Continued							
15G. TOTAL AMOUNT OF CONTRACT						\$89,738.88	
16. TABLE OF CONTENTS							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES			
X	A	SOLICITATION/CONTRACT FORM	1	X	I	CONTRACT CLAUSES	22
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	4	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
X	C	DESCRIPTION/SPECS./WORK STATEMENT	7	X	J	LIST OF ATTACHMENTS	26
X	D	PACKAGING AND MARKING	8	PART IV - REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	9		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	10		L	INSTRS., CONDS. AND NOTICES TO OFFERORS	
X	G	CONTRACT ADMINISTRATION DATA	13		M	EVALUATION FACTORS FOR AWARD	
X	H	SPECIAL CONTRACT REQUIREMENTS	17				
CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE							
17. <input checked="" type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)				18. <input type="checkbox"/> SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number			
19A. NAME AND TITLE OF SIGNER (Type or print)				20A. NAME OF CONTRACTING OFFICER DIANE L. COGER			
19B. NAME OF CONTRACTOR			19C. DATE SIGNED	20B. UNITED STATES OF AMERICA			20C. DATE SIGNED
BY (Signature of person authorized to sign)				BY (Signature of the Contracting Officer)			

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
HHSH258201300015CPAGE OF
2 43

NAME OF OFFEROR OR CONTRACTOR

LOS ANGELES, COUNTY OF 136990

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 95-6000927 DUNS Number: 056454895 Delivery: 12/31/2013 Appr. Yr.: 2013 CAN: 3280075 Object Class: 25627 FOB: Destination Period of Performance: 09/25/2013 to 12/31/2013 Title: Outpatient Clinical Treatment Services for Hansen's Disease Type of Contract: Firm Fixed-Price				
1	Procurement Plan Number NHDP 181 C 1877 The Contractor shall provide all services related to Outpatient Clinical Treatment Services for Hansen's Disease for the National Hansen Disease Program in accordance with the Statement of Work as attached. Obligated Amount: \$89,738.88				89,738.88
2	Option Period One Amount: \$336,520.80 (Option Line Item) 12/31/2013				0.00
3	Option Period Two Amount: \$336,520.80 (Option Line Item) 12/31/2014				0.00
4	Option Period Three Amount: \$336,520.80 (Option Line Item) 12/31/2015				0.00
5	Option Period Four Amount: \$336,520.80 (Option Line Item) 12/31/2016 Contracting Officer Representative (COR): Irma E. Guerra, BSN, MPH Director, Ambulatory Care National Hansen's Disease Program 1770 Physician Park Drive Baton Rouge, LA 70816 Telephone: 1-800-642-2477 Fax: 225-756-3806 Email: IGuerra@hrsa.gov Continued ...				0.00

CONTINUATION SHEET

 REFERENCE NO. OF DOCUMENT BEING CONTINUED
 HHSH258201300015C

PAGE 3 OF 43

NAME OF OFFEROR OR CONTRACTOR

LOS ANGELES, COUNTY OF 136990

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Contracts Office Point of Contact: Charisse Whitney National Hansen's Disease Program 1770 Physician Park Drive Baton Rouge, LA 70816 Telephone: 225-756-3785 Fax: 225-756-3786 The total amount of award: \$1,435,822.08. The obligation for this award is shown in box 15G.				

SECTION A – STANDARD FORM (SF) 26

This page is left blank intentionally.

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

B.1 Purpose of Contract

The purpose of this contract is to provide Hansen's Disease (HD) diagnosis, outpatient treatment, case management, and follow-up of persons diagnosed with HD and screening of their contacts.

B.2 Compensation Cost/Price

1. In consideration of the satisfactory performance of the services and tasks detailed in Section J— Attachment A-Statement of Work, the Contractor shall be compensated in accordance with the following amounts:

a) Base Period (September 25, 2013 – December 31, 2013)

The price for full performance of the base period under this contract will be \$89,738.88.

b) Option Period One (January 1, 2014- December 31, 2014)

It is estimated that the cost to the Government for full performance of Option Period One, if exercised, under this contract will be \$336,520.80.

Price for Four (4) Three (3) month intervals:

\$84,130.20
\$84,130.20
\$84,130.20
\$84,130.20

c) Option Period Two (January 1, 2015- December 31, 2015)

It is estimated that the total cost to the Government for full performance of Option Period Two, if exercised, under this contract will be \$336,520.80.

Price for Four (4) Three (3) month intervals:

\$84,130.20
\$84,130.20
\$84,130.20
\$84,130.20

d) Option Period Three (January 1, 2016- December 31, 2016)

It is estimated that the total cost to the Government for full performance of Option Period Three, if exercised, under this contract will be \$336,520.80.

Price for Four (4) Three (3) month intervals:

\$84,130.20
\$84,130.20
\$84,130.20
\$84,130.20

e) Option Period Four (January 1, 2017- December 31, 2017)

It is estimated that the total cost to the Government for full performance of Option Period Four, if exercised, under this contract will be \$336,520.80.

Price for Four (4) Three (3) month intervals:

\$84,130.20
\$84,130.20
\$84,130.20
\$84,130.20

2. The total Firm Fixed Price (FFP) for the Base Period is \$88,738.88. The total FFP for Option Period One (1), Option Period Two (2); Option Period Three (3); and Option Period Four (3) is \$1,345,813.20.

B.3. Wage Determination

This contract is subject to the Wage Determination No. 2005-2047, Revision No. 11, date of revision 06/15/2010.

SECTION C -- DESCRIPTION/SPECIFICATIONS/ STATEMENT OF WORK

C.1 Statement of Work

Independently and not as an agent of the Government, the Contractor shall furnish all personnel, material, facilities, services, and equipment as needed to perform the Statement of Work set forth in Section J (Attachment A) attached hereto and made part of this document.

C.2 Incorporation of Contractor's Proposal

It is understood and agreed that the Contractor shall, in meeting the requirements of this contract, perform the work in accordance with the Contractor's proposal to the Health Resources and Services Administration originally dated March 8, 2013, revised July 3, 2013 and July 25, 2013, provided however, that to the extent that any clauses of the articles of this contract are in conflict or inconsistent with any clauses of said proposal, the provisions of the articles of this contract shall control and shall supersede the provisions of said proposal; therefore, the contractor's proposal is hereby incorporated into the resultant contract.

SECTION D – PACKAGING AND MARKING

PAGE LEFT BLANK INTENTIONALLY

SECTION E – INSPECTION AND ACCEPTANCE

E.1 Inspection and Acceptance

The Contracting Officer Representative (COR), as a duly authorized representative of the Contracting Officer, shall assume the responsibilities for monitoring the Contractor's performance, evaluating the quality of services provided by the Contractor and performing final inspection and acceptance of all deliverables.

E.2 52.246-4 Inspection of Services—Fixed Price (AUG 1996)

(a) Definition. "Services," as used in this clause, includes services performed, workmanship, and material furnished or utilized in the performance of services.

(b) The Contractor shall provide and maintain an inspection system acceptable to the Government covering the services under this contract. Complete records of all inspection work performed by the Contractor shall be maintained and made available to the Government during contract performance and for as long afterwards as the contract requires.

(c) The Government has the right to inspect and test all services called for by the contract, to the extent practicable at all times and places during the term of the contract. The Government shall perform inspections and tests in a manner that will not unduly delay the work.

(d) If the Government performs inspections or tests on the premises of the Contractor or a subcontractor, the Contractor shall furnish, and shall require subcontractors to furnish, at no increase in contract price, all reasonable facilities and assistance for the safe and convenient performance of these duties.

(e) If any of the services do not conform with contract requirements, the Government may require the Contractor to perform the services again in conformity with contract requirements, at no increase in contract amount. When the defects in services cannot be corrected by re-performance, the Government may—

(1) Require the Contractor to take necessary action to ensure that future performance conforms to contract requirements; and

(2) Reduce the contract price to reflect the reduced value of the services performed.

(f) If the Contractor fails to promptly perform the services again or to take the necessary action to ensure future performance in conformity with contract requirements, the Government may—

(1) By contract or otherwise, perform the services and charge to the Contractor any cost incurred by the Government that is directly related to the performance of such service; or

(2) Terminate the contract for default.

SECTION F – DELIVERIES OR PERFORMANCE

F.1 FAR 52.252-2 Clauses Incorporated by Reference (FEB 1998)

The contract incorporates one or more clauses by reference with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. In addition, the full text of a clause may be accessed electronically at www.arnet.gov/far.

F.2 FAR 52.242-15 Stop-Work Order (AUG 1989)—Alternate I (APR 1984)

F.3 Observance of Federal Holidays

Official Holidays

New Year's Day	January 1 st
Martin Luther King's Birthday	3 rd Monday in January
Inauguration Day	3 rd Tuesday in January (every 4 th year)
Presidents' Day	3 rd Monday in February
Memorial Day	Last Monday in May
Independence Day	July 4 th
Labor Day	1 st Monday in September
Columbus Day	2 nd Monday in October
Veterans' Day	November 11 th
Thanksgiving Day	4 th Thursday in November
Christmas Day	December 25 th
Inauguration Day	Every fourth year, Washington, DC

For work to be performed at Government site(s):

1. No services or deliveries shall be performed, nor shall HRSA reimburse a contractor for work performed on Saturdays, Sundays, Federal legal holidays, holidays set forth by Presidential Executive Order and any other Government closures, including for inclement weather, unless otherwise provided for in the terms of the contract. The contractor may not bill for hours not worked.

2. When the Government site is closed, there may be a rare emergency situation or a necessity for critical work to continue where the Contracting Officer or the Head of Contracting Activity may authorize work at the fixed hourly rate set forth in the contract.

F.4 Period of Performance/Place of Performance

The period of performance shall be a base period of twelve (12) months with four (4) twelve (12) month option periods. The period of performance under this contract shall commence with the effective date of the contract (EDOC). The place of performance is at the contractor's site.

F.5 Articles or Services to be Furnished

1. All reports, processes, and product deliverables are subject to approval of the Contracting Officer Representative (COR).
2. All reports and documents shall have, at a minimum in the document header, the contract number, and the COR's name. All reports and documents shall have, at a minimum in the document footer, the author in the lower left corner, the page # of total # of pages in the center bottom of the page, and the date and /or version of the document (not the auto date) in the lower right corner.

F.6 Schedule of Deliverables

- a. The Contractor shall submit all items in the quantities and by the dates indicated to the COR.

(Base and Option Periods)

Deliverable	Quantity	Due Date
Outpatient Treatment	As required	Upon patient presentation in clinic
Hansen's Disease Surveillance Report	As requested	Upon confirmed HD Diagnosis
Semi-Annual Reports	2	1 NLT 30 days after June 30 1 NLT 30 days after December 31

In addition to the number of copies to be submitted as shown above, one copy of the final report shall be mailed directly to:

National Hansen's Disease Programs
Attn: Contracts Office
1770 Physicians Park Drive
Baton Rouge LA 70816

b. Reporting Requirements And Deliverables

1. The contractor shall submit the items in quantities and during the time periods indicated above to the following address:

National Hansen's Disease Programs
1770 Physicians Park Drive
Baton Rouge LA 70816

2. The Contractor shall deliver all items labeled per instructions, and in the quantity cited, and at the time indicated or before the time indicated in this Article.

- a. All deliverable reports are to carry at the top of the first page the following

information:

- 1) Contract number
- 2) Deliverable item number
- 3) Deliverable item delivery due date
- 4) Date of submission

- b. All deliverables items are to be separate physical entities.
- c. All deliverables are subject to the review and approval of the COR.

SECTION G – CONTRACT ADMINISTRATION DATA

G.1 Designation of Contracting Officer Representative (COR)

The person identified below is hereby designated as the Contracting Officer Representative (COR) for this contract. The responsibility of the COR is to ensure that the Government's technical objectives are met. To this end, the COR will provide necessary information, direction, coordination, etc., within the contractual work description. Issuance of changes which affect the articles, terms, or conditions of this contract will be accomplished through the Contracting Officer who is the **only** party authorized to bind the Government to contract:

Irma Guerra
Health Resources and Services Administration
National Hansen's Disease Program (NHDP)
1700 Physicians Park Drive
Baton Rouge, LA 70816
Phone Number: 225-756-3764
Fax Number: 225-756-3806
Email: iguerra@hrsa.gov

G.2 Contracting Officer's Representative's Responsibility

Technical Direction – The COR will provide the necessary information, direction, and coordination within the confines of the existing contractual work description in order for the contract to have a successful outcome for the government.

This includes providing technical direction to the Contractor to guide the contract effort in order to accomplish the contractual statement of work. This may include providing information to the Contractor for assistance in the interpretation of government provided information, specifications or technical portions of the work description, and where required by the contract, review and approval of product deliverables of the Contractor to the Government under the contract.

Contract Progress and Performance Management – The COR should prepare a performance report semiannually on the contractor's performance on this Contract. The minimal requirement is an annual performance report. Performance reporting on this Contract follows established government guidelines and is submitted to the Contractor and Contracting Officer with supporting documentation.

G.3 Restrictions on the Contracting Officer's Representative's Authority

Direction given by the COR to the Contractor must be within the parameters of the Statement of Work as stated in the Contract.

The COR may not issue any direction to the Contractor that:

1. Solicits a proposal, OR
2. Constitutes an assignment of additional work outside the Statement of Work of this Contract, OR
3. In any manner causes an increase in the total contract cost or the time required for contract performance, OR
4. Changes any of the express terms, conditions, or specifications of the Contract (i.e., changes in

the price or scope of work, instructions to start or stop work, approval of any actions that will result in additional charges to the government).

Issuance of changes that affect the articles, terms, or conditions of this Contract will be accomplished through the Contracting Officer, who is the only party authorized to bind the Government to contract and the only party who can determine if a direction is within the Statement of Work.

G.4 Key Personnel

Pursuant to the Key Personnel clause (HHSAR 352.242-70) referenced in SECTION I of this contract, the following individual(s) is (are) designated as Key Personnel and considered to be essential to the work being performed under this contract:

Title	Name
Administrator	Margaret Berumen

Contact Information for key personnel:

Outpatient Department and Specialty Care
Clinic Tower
1100 N. State St
Los Angeles, CA 90033
Telephone No. 323-226-6870
Email: mberumen@dhs.lacounty.gov

The person identified as the Key Personnel shall direct the necessary work and services toward fulfillment of the contractual requirements. Prior to removing, replacing, or diverting the specified individual(s), the Contractor shall notify the Contracting Officer in writing and reasonably in advance, and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the contract. No diversion shall be made by the Contractor without the written consent of the Contracting Officer, provided that the Contracting Officer may ratify in writing changes made due to events beyond the control of the Contractor, and such ratification shall constitute the consent of the Contracting Officer required by this clause. Examples of events beyond the control of the Contractor are: (1) prolonged sickness, (2) termination of employment, and (3) death. Key personnel, with the consent of the Contracting Officer, may be amended from time to time during the course of the contract to either add or delete personnel, as appropriate.

G.5 Submission of Invoices and Place of Payment

1. The Contractor shall submit monthly invoices. The monthly invoice shall be determined by dividing the total annual amount for services by 12 months.

2. The Contractor shall submit an original copy to the COR and one (1) copy to the below address:

Health and Resources Services Administration
National Hansen's Disease Programs
1770 Physicians Park Drive
Baton Rouge LA 70816
Attn: Financial Management Office
Reference Contract Number: HSHS258201300015C

**INVOICES WITHOUT ALL REQUIRED INFORMATION WILL BE DENIED UNTIL
THE PROPER INFORMATION IS SUBMITTED.**

3. For inquiries regarding receiving, inspection and acceptance, rejections, or technical issues, call your respective COR.
4. The Contractor agrees to include the following information on its invoice:
- Name and address of the Contractor same as on the contract;
 - DUNS number;
 - Invoice or voucher number;
 - Invoice or voucher date;
 - Dollar amount;
 - Contract number _____; order number _____; Date of Delivery or Service;
 - Description, quantity, unit of measure, unit price, and extended price of supplies delivered or services performed;
 - Information that supports request for payment; and
 - Name and complete mailing address where payment is sent.
5. Receiving Payment under this contract
- a. You **must** be able to accept electronic payments.
- b. Have a valid TIN and DUNS Number and be registered in the System for Award Management (SAM) database (<http://www.sam.gov>). The Contractor shall maintain registration during performance and through final payment of this contract.
- c. **Keep in mind if your bank merges with another bank or you change banks you are responsible for updating the data in the SAM database. For inquiries regarding payment, contact the Financial Management Office at (225) 756-3769.**

G.6 Electronic Funds Transfer

The Contractor shall designate a financial institution for receipt of electronic funds transfer payments and it shall be reported in Systems for Award Management (SAM) and shall be submitted in writing to the finance office set forth in Section G.5.5. All data stored in the CCR and ORCA has been transferred to the new Systems for Award Management (SAM) and can be found at

www.sam.gov. Contractors are encouraged to periodically review their file for accuracy and are required to re-register before their expiration date, which is the same date as their CCR expiration date. SAM will notify users by e-mail that their file is due to expire beginning 60 days prior to expiration, then 30 days and finally 15 days before expiration. Directions on how to navigate SAM can be found on the site's Home Page by clicking *Help* in the navigation bar at the top of the page.

G.7 Evaluation of Contractor's Performance

Interim and final evaluation of Contractor performance on this contract shall be conducted in accordance with FAR Subpart 42.15, and HHSAR 342.7001(d). Upon contract completion, a final evaluation of the Contractor's performance shall be completed by the Government; see Section J, Attachment D.

The Government will conduct an evaluation of Contractor's performance based on the completion of the tasks stated in the SOW. HRSA documents contractor performance using the Contractor Performance Assessment Rating System (CPARS) (www.cpars.gov). The evaluation shall be conducted by the COR and be comprised of an evaluation of contractor performance completed by the Contractor and Federal staff, and a review of progress reports and financial reports (deliverables).

SECTION H – SPECIAL CONTRACT REQUIREMENTS

H.1 Communication

Any HRSA communication products developed under this contract will require an additional separate clearance on an HHS-615 (for text and/or graphic publications and products that will be printed, posted on the Web, or disseminated through other electronic methods, such as by email) or an HHS-524A (for audiovisual products, including those that will be posted on the Web). Communication clearance for this contract itself does not satisfy the requirement to seek clearance of the specific HRSA communication products.

H.2 Printing and Duplicating

The printing of government documents **must** be accomplished through the Government Printing Office (GPO). Contractors and grantees shall not be used as sources of printing for the Department or OPDIVS. Therefore, the inclusion of printing in contracts and grants is prohibited unless authorized by the Joint Committee on Printing (JCP). All requests for waivers must go through the HHS Department Printing Officer. Contractors may prepare copy, illustrative material (forms etc.) and /or camera ready copy for the purpose of producing publications.

The Contractor shall not engage in, nor subcontract for, any printing (as the term is defined in Title 1 of the Government Printing and Binding Regulations in effect on the effective date of this contract) in connection with the performance of work under this contract; except that performance of a requirement under this contract involving less than 25,000 production units in the aggregate of multiple pages will not be deemed to be printing. A production unit is defined as one sheet, size 8.5 x 11 inches, one side only, and one color.

Regarding the use of private funds for printing, the regulations state that when appropriated funds are to be used to create information for publication, the printing of that information cannot be made available to a private publisher for publication without prior approval of the congressional Joint Committee on Printing by way of the office of HHS Department Printing Officer. For any questions, please contact the HHS Department Printing Officer at 301-594-3185.

H.3 Clearance/Production of Information Products/Services

The U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Public Affairs, requires clearance for any external communication products, which includes publications, audiovisual products, multimedia products, exhibits (including exhibit structures), conferences (including program/agenda books and other meeting materials), or public affairs services produced for or by HRSA through this contract as a deliverable. An external communication product is one that will be distributed outside of HRSA in any quantity. This clearance, which takes approximately 4 weeks, is obtained by the project officer through HRSA's Office of Communications.

It is the policy of HHS that HHS must be prominently and dominantly identified as the primary publisher/producer, to include the name of HHS and placement of the HHS logo, on all communication materials, including those produced for Government publications and Government printed matter by contractors.

The name of the U.S. Department of Health and Human Services and the Health Resources and Services Administration must be spelled out on the front cover of publications and on the opening and closing frames of audiovisual products. The HHS and HRSA logos must be displayed in addition to spelling out the names of the Department and the Agency. Use of the HHS and HRSA logos that include the names of the Department and the Agency as part of the graphics in the logos does not satisfy the requirement to spell out the names of HHS and HRSA. All publications and audiovisual products must display the month and year of issuance. The HHS and HRSA logos must be displayed on the front cover of any publications and on the opening and closing frames of any audiovisual products. The requirement for placement of the logos may be satisfied by displaying the HHS logo on the bottom left corner and the HRSA logo on the bottom right corner. The HHS logo should be larger than the HRSA logo. Government publications or other Government printed matter may not include the contractor's logo unless specifically authorized in accordance with agency policy and procedures (http://www.hhs.gov/web/policies/webpolicies/logopolicies/logos_contractors.html)

Communication products are any and all products intended for audiences outside the Agency, including but not limited to:

- reports, booklets, manuals, fact sheets, newsletters, brochures, flyers
- Internet publications
- press releases, advisories, other media materials (including press kits)
- exhibits, exhibit structures
- conferences, meeting materials (including program/agenda books)
- summaries, monographs, proceedings
- slides, overhead transparencies, posters
- audio and videotapes, films, CDs, DVDs, and other audiovisual products
- multimedia products, educational or information modules
- advertisements and/or scripts for radio, TV, Web, or other venue

Internal publications (no copies will be distributed outside of the Agency in print; electronically by any means, including by email or listserv; and will not be posted on the Internet) are exempted from this requirement. Where appropriate, the words Health Resources and Services Administration, Bureau ..., Office of, Division of ..., shall be included above the HRSA logo.

Title 44 of the U.S. Code requires that the printing of any publication developed under this contract shall be done by the Government Printing Office. Printing shall be coordinated through the Contracting Officer Technical Representative.

NOTE: OMB clearance must be obtained if you (the contractor) intend to survey or interview more than 9 people outside of HRSA and/or the Department, including grantees. *Failure on the part of the Contractor to comply with the printing and duplicating, and publication clearance requirements stated above will be deemed unauthorized services and reimbursement will be denied.*

H.4 Language Disclaimer

The views expressed in written conference materials, publications, audiovisual products, and by speakers and moderators at HHS-sponsored conferences, do not necessarily reflect the official policies of the U.S.

Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.

H.5 Rights in Data

The Contractor will be prohibited from copyrighting, publishing or disseminating information resulting from work performed under this contract, and/or, using data produced or obtained under this contract, and/or any other information or products provided by the Government, or which the Contractor develops, for any purpose other than performance under this contract without prior written approval from the Contracting Officer.

Ownership of Documents, Materials and Records: All documents, materials (including any computer code) or records provided to the Contractor, developed or maintained by the Contractor in the performance of this contract are deemed to be property of the Government.

H.6 Limited Use of Data

Performance of this effort may require the Contractor to access and use data and information proprietary to a Government agency or Government Contractor which is of such a nature that its dissemination or use, other than in performance of this effort, would be adverse to the interests of the Government and/or others.

Contractor and/or Contractor personnel shall not divulge or release data or information developed or obtained in performance of this effort, until made public by the Government, except to authorize Government personnel or upon written approval of the Contracting Officer (CO). The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as required in the performance of this effort. Nothing herein shall preclude the use of any data independently acquired by the Contractor without such limitations or prohibit an agreement at no cost to the Government between the Contractor and the data owner which provides for greater rights to the Contractor.

H.7 Disclosure of Information

Information made available to the Contractor by the Government for the performance or administration of this effort shall be used only for those purposes and shall not be used in any other way without the written agreement of the Contracting Officer.

The Contractor agrees to assume responsibility for protecting the confidentiality of Government records, which are not public information. Each Contractor or employee of the Contractor to whom information may be made available or disclosed shall be notified in writing by the Contractor that such information may be disclosed only for a purpose and to the extent authorized herein.

H.8 Confidentiality Agreement Requirement

The Contractor shall implement a confidentiality agreement related to all data provided by the Government staff. All Contractor staff that work with the Federal Government and are provided information and access to databases shall sign such an agreement and a copy of the signed agreement for each relevant staff member shall be submitted to the COR prior to receipt of relevant documents.

H.9. Homeland Security Presidential Directive-12

To perform the work specified herein the Contractor personnel may require access to sensitive data, regular access to HHS-controlled facilities and/or access to HHS information systems, the Government may require that this effort entail a background investigation.

- Upon receipt of the Government's notification of applicable Suitability Background Investigation required, the Contractor shall complete and submit required forms within 30 days of the notification. Additional submission instructions can be found at the NCI Information Technology Security Policies, Background Investigation Process: (<http://ais.nci.nih.gov/>).
- The Contractor shall submit a roster, by name, position and responsibility, of all staff working under the contract. The roster shall be submitted to the Contracting Officer Representative (COR), with a copy to the HRSA Division of Workforce Management and Contracting Officer, within 14 days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within fifteen (15) calendar days of the change. The COR will submit the list to the HRSA Personnel Security Officer for determination of the appropriate level of suitability investigations to be performed.

Contractors should ensure that the employees whose names they submit have a reasonable chance for approval. While delays in performance caused by successful investigations will be the Government's responsibility, delays associated with rejections will be the Contractor's responsibility. Typically, the Government conducts investigations and checks at no cost to the Contractor. Multiple investigations for the same position, whether- resulting from rejections or resulting from an employee's move to another position(s) or company, may at the Contracting Officer's discretion, justify reductions(s) in the contract price of no more than the cost of the extra investigation.

H.10. Food

It is the Department's policy that OPDIVs and STAFFDIVs shall not use appropriated funds (whether from an annual appropriation, multi-year appropriation, appropriated user fee, mandatory appropriation, gift funds, or reimbursements from such appropriations, etc.) to purchase food (whether for conferences or meetings; for meals, light refreshments, or beverages; or for Federal or non-Federal participants). Food and meals are not to be provided and are an unallowable expense.

H.11. System for Award Management (SAM)

The Contractor must be registered in the SAM database at www.sam.gov. "Registered in the SAM database" means that (1) the Contractor has entered all mandatory information, including the DUNS number or the DUNS+4 number, into the SAM database; and (2) The Government has validated all mandatory data fields and has marked the record "Active".

By submission of an offer, the Offeror acknowledges the requirement that a prospective awardee shall be registered in the SAM database prior to award, during performance, and through final payment of any contract, basic agreement, basic ordering agreement, or blanket purchasing agreement resulting from this

solicitation. If not registered in the SAM database within the time prescribed by the Contracting Officer, the Contracting Officer will proceed to award to the next otherwise successful registered Offeror

H.12. Medical Records

The contractor shall ensure the confidentiality of the record under the Privacy Act of 1974 and HIPAA as it relates to the release of medical information.

H.13. Quality Assurance

The contractor shall perform all the requirements identified in this contract. The contractor shall supervise the reviews in accordance with Government Auditing Standards. The COR shall review and approve all work products and deliverables submitted by the contractor in accordance with the terms and conditions identified under the contract.

HRSA reserves the right to obtain and review working papers from the contractor for the period beginning with the effective date of the contract through its termination. These reviews shall be conducted at HRSA's discretion at either the contractor's site or at the appropriate HRSA office. When reviewed at the HRSA's site, the working papers will be sent to the HRSA office for review and evaluation by HRSA staff. After completion of the review, HRSA may hold a conference with the contractor to discuss any issues. HRSA may choose to visit the contractor or subcontractor site during the audit to assess performance of the review. The contractor shall maintain an internal quality control program adequate to ensure that the requirements of the contract are met. As with the working paper review, HRSA reserves the right to obtain and review all working papers associated with the contractor's internal quality control program. These reviews shall be conducted at HRSA's site, the working papers will be sent to the HRSA office for review and evaluation by HRSA staff. After completion of the review, HRSA may hold a conference with the contractor to discuss any issues. HRSA may choose to visit the contractor and/or the subcontractor's site during the review to assess performance of the reviews.

SECTION I – CONTRACT CLAUSES

I.1 Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Contract Clauses

- A. FAR 52.252-2 Clauses Incorporated by Reference (FEB 1998) --This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at www.acquisition.gov/far.

<u>Clause No.</u>	<u>Title</u>	<u>Date</u>
52.202-1	Definitions	JAN 2012
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	APR 1984
52.203-6	Restrictions on Subcontractor Sales to the Government	SEPT 2006
52.203-7	Anti-Kickback Procedures	OCT 2010
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	JAN 1997
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity	JAN 1997
52.203-12	Limitation on Payments to Influence Certain Federal Transactions	OCT 2010
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	MAY 2011
52.204-6	Data Universal Numbering System (DUNS) Number	APR 2008
52.204-7	Central Contractor Registration (now System for Award Management (SAM))	AUG 2012
52.204-9	Personal Identity Verification of Contractor Personnel	JAN 2011
52.204-10	Report of Executive Compensation and First Tier Subcontractor Awards	AUG 2012
52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment	DEC 2010
52.215-2	Audit and Records--Negotiation	OCT 2010
52.215-8	Order of Precedence--Uniform Contract Format	OCT 1997
52.215-10	Price Reduction for Defective Cost or Pricing Data	OCT 1997
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other Than Pensions	JUL 2005
52.215-20	Requirements for Certified Cost or Pricing Data	OCT 1997
52.215-21	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data -- Modifications	OCT 1997
52.219-14	Limitations on Subcontracting	NOV 2011
52.222-1	Notice to the Government of Labor Disputes	FEB 1997
52.222-3	Convict Labor	JUN 2003
52.222-17	Nondisplacement of Qualified Workers Under Service Contracts	JAN 2013
52.222-21	Prohibition of Segregated Facilities	FEB 1999
52.222-26	Equal Opportunity	MAR 2007
52.222-35	Equal Opportunity for Veterans	SEP 2010
52.222-36	Affirmative Action for Workers with Disabilities	OCT 2010

<u>Clause No.</u>	<u>Title</u>	<u>Date</u>
52.222-37	Employment Reports Veterans	SEP 2010
52.222-38	Compliance with Veteran's Employment Reporting Requirements	SEPT 2010
52.222-41	Service Contract Act of 1965	NOV 2007
52.222-42	Statement of Equivalent Rates for Federal Hires	MAY 1989
52.222-43	Fair Labor Standards Act and Service Contract Act-Price	SEPT 2009
52.222-54	Adjustment Employment Eligibility Verification	JUL 2012
52.223-3	Hazardous Material Identification and Material Safety Data	JAN 1997
52.223-5	Pollution Prevention and Right-to-Know Information	MAY 2011
52.223-6	Drug-Free Workplace	MAY 2001
52.223-10	Waste Reduction Program	MAY 2011
52.224-1	Privacy Act Notification	APR 1984
52.224-2	Privacy Act	APR 1984
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.227-1	Authorization and Consent	DEC 2007
52.227-14	Rights in Data-General	DEC 2007
52.227-17	Rights in Data-Special Works	DEC 2007
52.228-7	Insurance-Liability to Third Persons	MAR 1996
52.229-3	Federal, State and Local Taxes	APR 2003
52.230-2	Cost Accounting Standards	MAY 2012
52.230-3	Disclosure and Consistency of Cost Accounting Practices	MAY 2012
52.230-6	Administration of Cost Accounting Standards	JUN 2010
52.232-1	Payments	APR 1984
52.232-9	Limitation on Withholding of Payments	APR 1984
52.232-13	Notice of Progress Payments	APR 1984
52.232-17	Interest	OCT 2010
52.232-18	Availability of Funds	APR 1984
52.232-23	Assignment of Claims	JAN 1986
52.232-25	Prompt Payment	OCT 2008
52.232-33	Payment by Electronic Funds Transfer-Central Contractor Registration (now known as System for Award Management (SAM))	OCT 2003
52.232-38	Submission of Electronic Funds Transfer Information with Offer	MAY 1999
52.232-99	Providing Accelerated Payment to Small Business Subcontractor	AUG 2012
52.233-1	Disputes	JUL 2002
52.233-2	Service of Protest	SEPT 2006
52.233-3	Protest After Award-Alternate I (JUN 1985)	AUG 1996
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.237-3	Continuity of Services	JAN 1991
52.237-7	Indemnification and Medical Liability Insurance	JAN 1997
52.239-1	Privacy or Security Safeguards	AUG 1996
52.242-17	Government Delay of Work	APR 1984
52.242-13	Bankruptcy	JUL 1995
52.243-1	Changes-Fixed Price (AUG 1997) - Alternate I	APR 1984

<u>Clause No</u>	<u>Title</u>	<u>Date</u>
52.244-2	Subcontracts	OCT 2010
52.244-5	Competition in Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	DEC 2010
52.246-25	Limitation of Liability-Services	FEB 1997
52.249-2	Termination for Convenience of the Government (Fixed Price)	MAY 2004
52.249-8	Termination (Fixed Price)	APR 1984
52.253-1	Computer Generated Forms	JAN 1991

A. Department of Health and Human Services Acquisition Regulation (HHSAR) (48 CFR Chapter 3) (<http://www.hhs.gov/policies/hhsar/subpart301-1.html>)

<u>Clause No.</u>	<u>Title</u>	<u>Date</u>
352.201-70	Paperwork Reduction Act	JAN 2006
352.202-1	Definitions	JAN 2006
352.224-70	Privacy Act	JAN 2006
352.227-70	Publications and Publicity	JAN 2006
352.228-7	Insurance - Liability to Third Persons	DEC 1991
352.231-70	Salary Rate Limitation	JAN 2010
352.233-71	Litigation and Claims	JAN 2006
352.242-71	Tobacco-free Facilities	JAN 2006
352.242-70	Key Personnel	JAN 2006
352.242-73	Withholding of Contract Payments	JAN 2006
352.242-74	Final Decisions on Audit Findings	APR 1984
352.270-10	Anti-Lobbying (applies if contract exceeds \$100,000)	JAN 2006
352.270-1	Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities	JAN 2001

I.2. Options

a. FAR 52.217-8, OPTION TO EXTEND SERVICES (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within the period specified in the Schedule

b. FAR 52.217-9, OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

- (a) The Government may extend the term of this contract by written notice to the Contractor within twelve (12) months, provided that the Government shall give the Contractor a preliminary written notice of its intent to extend at least sixty (60) days before the contract expires. The preliminary notice does not commit the Government to an extension.
- (b) If the Government exercises these options, the extended contract shall be considered to include this option provision.
- (c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed sixty (60) months.

SECTION J – LIST OF ATTACHMENTS

J.1 The following attachments are made part of this solicitation:

Attachment	Title	No. of Pages
A	Statement of Work	11
B	Billing Instructions	2
C	CPARS Information Sheet	1
D	A Manual for the Care of Hansen's Disease in the United States	49
E	Wage Determination No. 2005-2047 Revision No. 11; Date of Revision 06/15/2010	10
F	Office of Small and Disadvantaged Business Utilization Small Business Subcontracting Plan	13

ATTACHMENT A - STATEMENT OF WORK

TITLE: AMBULATORY CARE PROGRAM

I. BACKGROUND

The legislative authority for the National Hansen's Disease Programs is Public Law 99-117, Section 2. (a.), Section 320, and is guided by DHHS regulations. The Ambulatory Care Program was initiated in 1981 as a consequence of the closing of the U.S.P.H.S. hospitals. Historically, persons with HD were provided care by those facilities in the U.S. In order to continue the mandate of the legislative authority, a Contract Care Program was developed to provide these services in communities where the majority of people with HD live. The current Outpatient HD Clinics are located in the states of Arizona, Arkansas, California, Georgia, Florida, Illinois, Massachusetts, New York, Puerto Rico, Washington, and Texas.

Hansen's disease is a chronic infectious disease of low communicability, caused by the acid-fast Mycobacteria, *M. leprae*. It affects the skin and peripheral nerves in the cooler parts of the body. It is effectively treated by multidrug therapy consisting of Dapsone, Rifampin, and Clofazimine. Untreated, it can lead to loss of sensation in the affected areas, leading to trauma, infection, and eventually to deformity and disability. It is the goal of the National Hansen's Disease Program to prevent deformity and disability by raising awareness about Hansen's disease, increasing the detection of its' early signs, and initiating treatment early in the disease process.

II. PURPOSE/GENERAL DESCRIPTION

The purpose of this contract is to provide Hansen's Disease (HD) diagnosis, outpatient treatment, case management, and follow-up of persons diagnosed with HD and screening of its contact in Los Angeles, CA area. The number of patients expected for the service area is identified below. It is estimated that these patients will require 4 outpatient visits annually during the period of this Contract. The patient population with HD in the U.S. is multi-ethnic. It is expected that the Contractor be conversant with an accepted multi-cultural approach in the provision of patient care services.

Service Area:
Los Angeles

Number of Patients
589

A. Eligibility for Services

The contractor shall be responsible for providing outpatient care as described herein to those persons designated as eligible for treatment. The contractor shall validate the patient's eligibility before rendering services. When the eligibility status of an individual patient is unclear, the contractor shall obtain guidance and approval from the Project Officer. Patients are considered eligible under the following circumstances:

1. **HD Patient** – Any individual in the continental United States and Territory of Puerto Rico who needs to have HD ruled out as a diagnosis, or has been diagnosed as having HD, is eligible for care under this contract.
2. **HD contact** – Any person who has lived in the same household with a new HD patient in the three year period prior to the diagnosis and the beginning of treatment, shall be examined. (See HD Manual "Contact Follow-Up.")

B. The Contractor shall provide all personnel, material, adequate and accessible facilities, services, and equipment required to meet the requirements of this Contract.

1. **Hospital and/or Health Care Facility** – The facility shall JCAHO accredited or certified by an accredited certifying agency. Any conditional accreditation will be accompanied with a copy of the evaluation report.
2. **Availability** - Hours of operation should be adequate to support the HD patient population in the area. The contractor shall provide the facility hours and the clinic hours. Also include emergency and after hour provisions.
3. **Accessibility** – The facility shall be handicap accessible, including access through public transportation.
4. **Quality Assurance** - The facility shall provide a brief description of their Quality Assurance Plan. A sample of the satisfaction survey must be included in the response to this proposal
5. **Key Personnel**
Key personnel in this Contract are considered essential to the work being performed. This includes Project Director; Primary Physician; and HD Clinic RN.
6. **Multidisciplinary Team**
The multidisciplinary team shall provide services through the HD Contract. These Providers shall be licensed to practice, certified in their specialty, culturally competent, experienced in caring for the targeted population, and have appropriate consultative backup. **Resumes and proof of professional licensure shall be provided.** This team shall include:
 - a. Physician (part-time)
 - b. Nurse (part-time)
 - c. ENT
 - d. Ophthalmologist
 - e. Occupational Therapist
 - f. Physical Therapist
 - g. Orthopedist
 - h. Orthotist
 - i. Podiatrist

It is estimated that a routine, uncomplicated patient visit for HD services can be completed in 20 minutes, and visit frequency for the monitoring of chemotherapy is an average of four times a year. New cases may require 40 minutes to an hour for assessment. About 150 – 200 new cases are diagnosed each year in the United States. It is estimated that 20% of the patient population may have complications such as reaction, eye, hand, or foot problems which require more time during a clinic visit.

- C. The Contractor shall serve as HD consultant and resource in the community and in the geographic area identified in Attachment A, Statement of Work.

III. SPECIFIC TASKS

The purpose of the Outpatient Hansen's Disease Program is to provide outpatient medical and diagnostic services for HD and its related conditions. Services to be provided through this contract, according to the following protocol include:

Task 1. Patient Assessment:

Evaluation of a patient with suspected or confirmed HD shall include a complete history and physical exam as outlined in the HD Manual (Page 7, Patient Assessment).

Hansen's disease affects the skin, peripheral nerves, anterior part of the eyes, and the nasal area. In the advanced form of the disease (Lepromatous leprosy), it can cause gynecomastia and testicular atrophy in males. A complete physical assessment of the patient is necessary. Diagnostic criteria include the presence of anesthetic lesions with *M. leprae* in skin smears or biopsies, and sometimes, peripheral nerve enlargement.

Eyes: Examine the eye for inflammation, complete closure, and pupil size. In patients with borderline lepromatous or lepromatous disease, an ophthalmological exam shall be done to rule out eye involvement in this disease.

Skin: Hypo- or hyper-pigmented flat or raised lesions, are most commonly found on the face, extremities, buttocks, or thighs. Absence of sweating, hair loss, thinning of eyebrows, nodular thickening of earlobes, or changes in texture of the skin may also be present.

Nerves: Peripheral nerves may be enlarged or tender. The ulnar, median, radial cutaneous, posterior tibial, and peroneal nerves are most commonly affected. In patients with anesthesia of the hands or feet, ulcerations, wounds or scars without history of pain, muscle atrophy, or deformity may be present. A common complaint is pain in the extremities and a burning sensation in the soles of the feet.

Task 2. Diagnostic Studies:

Punch Biopsy: A 4 mm punch biopsy or larger is needed for diagnosis.

Skin Smears: These may be done on initial exam on all patients if experienced personnel are available. (See HD Manual, Forms and Procedures, Appendices C and D (Attachment D).)

Task 3. Laboratory Monitoring:

I. Recommended Laboratory Tests and Frequency							
	Initial visit	2 nd visit (1-2 months)	3 m	6 m	12 m	18 m	24 m

CBC + platelets	X	X	X	X	X	X	X
AST	X		X	X	X	X	X
ALT	X		X	X	X	X	X
CRP	X	x	X	X	X	X	X
BUN	X						
Creatinine	X						
Bilirubin	X						
G6PD	X						
Hepatitis B*							
Hepatitis C*							

*Screen for these if patient requires prednisone for reaction

PCR Assay (Polymerase Chain Reaction)

In a non-endemic population, the sensitivity and specificity of PCR assay recommend its use primarily to identify *M.leprae* when acid-fast organisms are discernible but atypical clinical or histopathologic features are obscuring the diagnosis. The Assay is not highly informative when acid-fast bacilli are not detectable by light microscopy. (Am J Clin Pathol 1998; 109:642-646) To further determine whether this Assay would be clinically appropriate, contact Dr. David Scollard, Chief, Clinical Branch, NHDP, at 225-756-3713

Task 4. Treatment

The HD Manual in the Appendix provides guidelines which shall be used to determine treatment of HD under this contract.

The Treatment Protocol for Hansen's Disease in the U.S. is multi-drug therapy which includes the drugs Dapsone, Rifampin and Clofazimine. Medications used for the treatment of reaction in HD are prednisone, clofazimine, and thalidomide. Alternative anti-microbial agents include minocycline, and clarithromycin, (See NHDP website, www.hrsa.gov/hansensdisease.)

A. Recommended Treatment Regimens-Adults

Following are the general NHDP treatment recommendations. The recommendations are for daily rifampin, and for longer duration of treatment than the WHO protocols, largely due to WHO's cost considerations for developing countries. Treatment that is more intensive and of longer duration is medically preferable.

Treatment guidelines for immunologically competent individuals, (e.g. those without immunodeficiency, immunosuppression, prolonged corticosteroid use, etc.) are as follows:

Adults		
Tuberculoid (TT & BT) (WHO classification Paucibacillary, "PB")		
Agent	Dose	Duration
Dapsone	100 mg daily	12 months, and <u>then therapy discontinued</u>
Rifampicin	600 mg daily	

Adults		
Lepromatous (LL, BL, BB) (WHO classification Multibacillary, "MB")		
Agent	Dose	Duration ^a
Dapsone	100 mg daily	24 months, and <u>then therapy discontinued</u>
Rifampicin	600 mg daily	
Clofazimine ^b	50 g daily	

a. The recommended durations of treatment are sufficient, even though large numbers of dead bacilli may remain in the tissues for several years, before they are eliminated by physiological processes. There is no evidence that additional, prolonged treatment hastens the elimination of these dead organisms. For immunologically compromised patients, these protocols may be modified, and consultation with the NHDP is recommended.

b. Clofazimine, used for decades to treat HD around the world, is no longer available on the open market. Because it is no longer distributed commercially, the only way we can obtain the drug in the U.S. is to once again treat it as an investigational new drug (IND). The NHDP holds this IND for its use in treating HD in the U.S.

In order for physicians to obtain the drug for treating HD, they will have to be registered as an

investigator under the NHDP IND. This will require submitting a signed FDA form 1572, providing a curriculum vitae, and obtaining and maintaining local Institutional Review Board (IRB) approval. A packet of information will be provided including everything that is needed for submission to the local IRB, e.g. treatment protocol, sample consent form and prescribing information. The NHDP provides guidance in this process but cannot obtain approval for physicians at any other clinic in the United States. Further information about this process can be obtained from :

Renee Painter
 Administrative Officer, Clinical Branch
 National Hansen's Disease Programs
 1770 Physicians Park Drive
 Baton Rouge, LA 70816

B. Recommended Treatment-Children

The occurrence of leprosy in children In the United States is rare. We strongly recommend contacting the NHDP for management of leprosy in children; the following are general guidelines:

Treatment for children		
Tuberculoid (TT & BT) (WHO Paucibacillary, "PB")		
Agent	Dose	Duration
Dapsone	1 mg/ Kg daily	12 months, and <u>then therapy discontinued</u>
Rifampicin	1-2 mg/ Kg daily	
Treatment for children		
Lepromatous (LL, BL, BB) (WHO Multibacillary, "MB")		
Agent	Dose	Duration
Dapsone	1 mg/ Kg daily	24 months, and <u>then therapy discontinued</u>
Rifampicin	10-20 mg/ Kg daily (not > 600)	
Clofazimine	1.0 mg/ Kg daily ^c	

c. As there is no formulation less than 50 mg, and the capsule should never be cut open, alternate day dosing may be used at 2 mg/kg.

THIS PAGE LEFT BLANK INTENTIONALLY

Task 5. Reaction

Leprosy reactions are acute hypersensitivity "reactions" to the *M. leprae* organism which may occur in 25% to 50% of all HD patients sometime during the course of the disease. There are no predictors of which patients will develop reaction, other than patients with tuberculoid disease do not develop reactive episodes, and these are less frequent in patients taking clofazimine. There are two types of reaction, Reversal Reaction, or Type I Reaction, and Erythema Nodosum Leprosum, or ENL, which is Type II Reaction.

Reactions are a major cause of peripheral nerve damage, so the goal of management in treating reaction is preventing nerve damage. Drugs commonly used are corticosteroids, clofazimine, and thalidomide. (For guidance on management of Reaction, call the NHDP at 1-800-642-2477.)

Thalidomide is very effective in controlling ENL, and is the drug of choice if not contraindicated. The drug is very teratogenic and causes severe birth defects if taken by women during pregnancy.

In the U.S., Thalidomide is available to the prescribing physician and the dispensing pharmacist by registering with Celgene's System for Thalidomide Education and Prescribing Safety (STEPS) program.

Task 6. Ancillary Services

Due to the multi-faceted aspects of this disease, patients shall be referred to the following ancillary medical services for treatment of complications as necessary:

- a. Dermatology
- b. ENT
- c. Ophthalmology
- d. Orthotics
- e. Podiatry
- f. Orthopedics

Task 7. Rehabilitation Services

An efficient and comprehensive rehabilitation program in the management of insensitive limbs secondary to HD shall incorporate physical therapy, occupational therapy, pedorthics, and patient education. Rehabilitation goals aimed at minimizing loss of nerve function, ulceration, amputation, and ultimate disability, are best achieved utilizing interdisciplinary rehabilitation practices.

- A. **Occupational Therapy** – Services required for the performance of this Contract include performing hand screens and reporting changes in sensory and motor function to the physician, teaching prevention of disability, providing wound care, splinting and casting,

recommending assistive devices and safety equipment, pre-and post-surgical therapy for HD orthopedic procedures, and in collaboration with the medical staff, identifying candidates for reconstructive surgery.

1. **Hand Screens** – These are a means of assessing the HD patient's risk category for hand problems, and for developing a care plan for their prevention and treatment.
2. The sensory testing device uses the Semmes-Weinstein Monofilaments for sensory threshold detection. The Hand Screen consists of a set of five (5) calibrated nylon filaments mounted on a small rod, which measure levels of cutaneous touch and pressure on a scale of 2.83 to 6.65. The normal threshold level is 2.83. The motor system is tested through a standard Manual Muscle Test.

B. Physical Therapy services include the following:

1. **Foot Screens** – The Foot Screen has been proven to accurately identify patients who are at risk of developing deformities as a result of insensitivity, and also provides a baseline for determining the extent of foot disabilities.
2. The Semmes-Weinstein Monofilaments for the Foot Screen are designed to deliver a 10 gram force when properly applied. The foot set of filaments consist of a set of three calibrated nylon filaments include the following: 4.17 (normal sensation), 5.07 (protective sensation), 6.03 (deep pressure). The motor system is tested through a standard Manual Muscle Test.

C. Frequency of Performance:

1. Hand and foot screens shall be done for new patients at the time of diagnosis, and on a quarterly basis as patients are scheduled for laboratory monitoring during chemotherapy.
2. Screens should also be performed as clinically necessary on any patient complaining of muscle weakness, decrease in sensation, or change in function.

The hand and foot filament sets for the Ambulatory Care Clinics may be obtained by calling 1-800-642-2477. The NHDP Rehabilitation Department Staff are also available for consultation as necessary.

Task 8. Patient and Professional Education

Appropriate treatment of stigmatizing disease like HD involves concerns about deformity, disability, isolation, job loss, and being a source of infection to their families. Awareness of these patient concerns will more likely ensure patient compliance with treatment.

In order to achieve its objective, which is the prevention of deformity and disability, the patient assessment, hand and foot screens, HD monitors, and contact exam shall be used to educate patients and family about HD.

The majority of healthcare providers in the U.S. are not aware of HD in the population. Providers serving populations from endemic areas shall be targeted for educational services on HD in order to increase their index of suspicion for the disease.

Educational materials are available from the NHDP (See Appendix, HD Manual, "Resources").

Task 9. Other Services

- A. Referrals to NHDP** – Physicians at NHDP in Baton Rouge, Louisiana may authorize referrals on a case-by-case basis
- B. Patient Transportation** – Reimbursement for travel to the HD Clinics may be provided for indigent patients through this contract when it is deemed necessary by the HD clinic staff.
- C. Subcontractors** - The contractor shall provide all necessary health services related to HD either directly or through subcontractors. The contractor is responsible for payments to subcontractors.
- D. Third Party Reimbursement** – The contractor shall screen all patients for any type of medical coverage to obtain third party reimbursement.

Task 10. Reporting Requirements (See Appendix, HD Manual, Forms and Procedure)

- A. Leprosy Surveillance Form** –The NHDP maintains a National HD Registry for all patients diagnosed in the U.S.A. The Hansen's Disease Surveillance Form is required on all newly-diagnosed patients. Cases diagnosed outside the U.S. must be evaluated for previous HD treatment, and if necessary, a biopsy done to establish clinical status and need for further medical treatment for HD.

The Form can be found on the NHDP website, www.hrsa.gov/hansens, and should be sent to NHDP as soon as the diagnosis is confirmed. Also, a copy of the form should be sent to the local and/or State Health Department. The HD Surveillance Form should be mailed or faxed to:

NHDP
ATTN: Medical Records
1770 Physicians Park Drive
Baton Rouge, LA 70816
Fax: 225-756-3706

B. The contractor shall submit, **semi-annually**, a password-protected electronic report on CD generated with the use of Microsoft Access or compatible database, with the following information:

1. Demographics:
 - a. Name of patient
 - b. Birth date
 - c. Gender
 - d. Social Security number
 - e. Type of disease
 - f. Date of diagnosis
 - g. Address
 - h. Clinic activity status of patient:
 - A-Active (attends clinic for services)
 - C-Contact (household member of patient)
 - D-Deceased
 - LF-Lost to Follow-Up (unable to contact after several attempts)
 - RS-Refused Supervision (contacted and nonresponsive)
 - R-Relocated (relocated from area of services)
 - S-Suspect (Pending rule/out of HD)
2. Medication:
 - a. Start and stop date
 - b. Type of medication protocol
 - 1) Recommended regimen (Dapsone, Rifampin, Clofazimine)
 - 2) Other MDT (list medications)
 - 3) Treatment completed, a or b above; continues on monotherapy (specify continued medication)
3. Reaction
 - a. Type
 - b. Medication start and stop dates
4. Hand and Foot Screens-date and grade (**per WHO recommendations**)
5. Clinic visit and date
6. Consult visit and date
7. Referral to NHDP and date
8. Hard copy of the following documents performed during the reporting period: (See HD Manual, Forms and Procedures)
 - a. Hand Screens
 - b. Foot Screens
 - c. Change of Information Form
 - d. Quality Assurance Form

Other reports and information requested by the Project Officer for Program Evaluation of the services provided under this Contract.

Task 11. Reference Material

- A. The HD Manual in the appendix provides guidelines for treatment of Hansen's disease in the U.S.
- B. Reporting forms are available from the National Hansen's Disease Program or the website listed below.
- C. Questions regarding treatment regimens shall be directed to the Clinical Branch at NHDP. More information is available about HD and our services on the NHDP website, www.hrsa.gov/hansens or by calling 1-800-642-2477.
- D. The online course, "*Lower Extremity Amputation Prevention and Treatment of the Neuropathic Foot*," is highly recommended for physicians, nurses, and therapists providing services through this contract. This course can be found at www.hrsa.gov/leap/brochure.htm.

ATTACHMENT B - BILLING INSTRUCTIONS

A. RECEIVING PAYMENT UNDER ATTACHED AWARD

1. You **must** be able to accept electronic payments.
2. Have a valid TIN and DUNS Number and be registered in the System for Award Management (SAM) database (<http://www.sam.gov>). The Contractor shall maintain registration during performance and through final payment of this contract.

Keep in mind if your bank merges with another bank or you change banks you are responsible for updating the data in the SAM database. For inquiries regarding payment, call the Financial Management Office at (225) 756-3769.

B. SUBMITTING INVOICES

Before submitting an invoice, you should make sure that the invoice contains the following information:

1. The Contractor shall submit invoices/vouchers in Microsoft Word or PDF format using **Standard Form SF1034** "Public Voucher for Purchases and Services Other than Personal" and include the following information:
 - Name and address of the Contractor same as on the contract;
 - DUNS number;
 - Invoice or voucher number;
 - Invoice or voucher date;
 - Dollar amount;
 - Contract number _____; order number _____; Date of Delivery or Service;
 - Description, quantity, unit of measure, unit price, and extended price of supplies delivered or services performed;
 - Information that supports request for payment; and
 - Name and complete mailing address where payment is sent.
2. Inquiries:
 - Regarding payment**, call (225) 756-3769;
 - Regarding receiving, inspection and acceptance, or technical issues**, call your Contracting Officer Representative;
 - Regarding suspension or rejection** call your Contract Specialist.

INVOICES WITHOUT ALL REQUIRED INFORMATION WILL BE DENIED UNTIL THE PROPER INFORMATION IS SUBMITTED.

Note: Your respective COR does not have the authority to (1) solicit proposals, (2) modify the stated terms of the award (i.e. change in price, change in scope of work), (3) issue instructions to the contractor to start or stop work, or (4) approve any action that will result in additional charges to the government. These changes are the sole responsibility of the Contracting Officer. The Government will not be responsible for cost overruns or unauthorized procurements made by the vendor.

PRIVACY ACT STATEMENT

The information requested on this form is required under the provisions of 31 U.S.C. 82b and 82c, for the purpose of disbursing Federal money. The information requested is to identify the particular creditor and the amounts to be paid. Failure to furnish this information will hinder discharge of the payment obligation.

ATTACHMENT C – CPARS INFORMATION SHEET

The Contractor Performance Assessment Reporting System (CPARS) is the Department of Defense (DoD) Enterprise Solution for collection of contractor Past Performance Information (PPI) as required by the Federal Acquisition Regulation (FAR). CPARS is a web-enabled application that collects and manages a library of automated contractor report cards. A report card assesses a contractor's performance and provides a record, both positive and negative, on a given contract for a specific period of time. Each report card is based on objective facts and is supported by program and contract management data. Use of CPARS promotes report card consistency, increases data integrity, and motivates improved contractor performance. For more information, see www.cpars.gov

ATTACHMENT D - A Manual for the Care of Hansen's Disease in the United States

A MANUAL FOR THE CARE OF

HANSEN'S DISEASE

IN THE
UNITED STATES

National Hansen's Disease Programs
Ambulatory Care Program
1770 Physicians Park Drive
Baton Rouge, Louisiana 70816
Phone: 1-800-642-2477
Website: www.hrsa.gov/hansensdisease

NHDPVACP
Rev. 8/2012

TABLE OF CONTENTS

	<u>Page</u>
Introduction	1
Mission	
Eligibility	
Objective	
Background	
Epidemiology	2
Bacteriology	2
Management of Hansen's Disease	2
Clinical Aspects	2
Effects of Hansen's Disease on Peripheral Nerves	3
The Peripheral Nerves	3
Surgery	4
Silent Neuritis	4
HD and Pregnancy	5
HD and Children	5
Testicular HD	6
Diagnostic Criteria	6
Schedule of Services	6
Patient Assessment	7
Laboratory Monitoring.....	8
Treatment of HD in the U.S.	8
Reactions in HD	13
Rehabilitation Services	15
Consultant Services	16
Contact Follow-UP.....	16
Reporting Requirements	17
Patient Education	17
Referrals to NHDP	17
Ambulatory Care Program	17
Private Physician Program	17
Resources	18
Forms and Procedures	

NATIONAL HANSEN'S DISEASE PROGRAM

A MANUAL FOR THE CARE OF HANSEN'S DISEASE IN THE UNITED STATES

INTRODUCTION

MISSION

The National Hansen's Disease Program (NHDP) is an activity in the Department of Health and Human Services (DHHS), Health Resources and Services Administration (HRSA), and the Healthcare Systems Bureau. It is authorized by Public Law 99-117, Section 2. (a), Section 320 and is guided by DHHS regulations. The NHDP is charged with the responsibility of providing Hansen's disease (HD) treatment for individuals with this disease through the NHDP, in Baton Rouge, Louisiana, and through its Ambulatory Care Program.

ELIGIBILITY

Any individual living in the United States and Puerto Rico may receive outpatient medical care for the diagnosis and treatment of HD and its complications. Contacts of these patients are also eligible for services as described by NHDP policy (see "Contact Surveillance" in this Manual)

OBJECTIVE

The goal of the National Hansen's Disease Program is to prevent deformity and disability from HD through early diagnosis and treatment. The purpose of this Manual is to serve as a resource for the diagnosis, care, and treatment of HD in the United States (U.S.).

BACKGROUND

The NHDP in the United States has a 100-year history of caring for people diagnosed with this disease. It began in 1896 in Carville, Louisiana, with the Daughters of Charity of St. Vincent de Paul who provided basic services to a small group of patients from New Orleans. In 1921 it became the federally-funded Gillis W. Long Hansen's Disease Center and the only inpatient facility for HD in the country.

In the early 40's, the use of sulfone therapy by Dr. Guy Faget at the Center resulted in the development of dapsone as a bactericidal agent against Mycobacterium leprae, the organism that causes the disease. This led to the greatest change in patient care, for patients could now be discharged from "Carville" and new patients could be treated on an outpatient basis.

The year 1960 Dr. Paul Brand, FRCS, FACS, an orthopedic surgeon, initiated rehabilitative procedures at Carville which effectively decreased the frequency of amputation of the lower extremities. These procedures have been incorporated into what is now LEAP, or Lower Extremity Amputation Prevention, the core of the Foot Seminars at the NHDP.

In 1981, the Federal Government initiated the Ambulatory Care Program (ACP), which provides HD medical care through Outpatient Clinics in the U.S. and Puerto Rico. Services provided by these Clinics include diagnosis and treatment of HD and related conditions, laboratory monitoring, consultant services, and patient and community education.

In January, 2000, the NHDP relocated its services at Carville to Ochsner Medical Center campus in Baton Rouge, LA, and now functions as the primary Outpatient Referral Center for the diagnosis and treatment of HD.

EPIDEMIOLOGY

The NHDP has responsibility for the National Hansen's Disease Registry, which is maintained through the submission of HD Surveillance Forms by private providers, and from the Outpatient HD clinics. California, Florida, Hawaii, Louisiana, Massachusetts, New York, and Texas collectively accounted for the largest number of the total reported cases. Although the number of cases reported annually is affected considerably by immigration patterns, the average number of annual cases reported over the past decade is 130.5.

Hansen's disease occurs in all age groups with a U.S. median age at diagnosis of 35.0 years. The disease exhibits a gender bias with twice as many male cases as female. A race/ethnicity breakdown shows that three fourths of the reported cases are represented by the Asian/Pacific Islander and White Hispanic groups, but fully 50% of the endemic cases are classified as White, Not Hispanic. (See "Data & Statistics" at www.hrsa.gov/hansensdisease 3 for more information)

BACTERIOLOGY

HD is caused by Mycobacterium leprae, a slow-growing, acid-fast bacillus. The incubation period for HD may be two-five years, although it can be as long as 15-20 years or more. The disease is probably spread through airborne droplets from the nasal mucosa and upper airways of a person with untreated disease, or through prolonged skin contact with this person. Armadillos may also carry the disease. The communicability of HD is very low, however, and about 95% of the world's population has a natural immunity to this bacillus. A person with HD becomes non-communicable within one week of starting treatment.

MANAGEMENT OF HANSEN'S DISEASE

CLINICAL ASPECTS OF HANSEN'S DISEASE

HD affects the skin, peripheral nerves, eyes, and mucous membranes of the upper respiratory tract, especially the nose. Nerve damage caused by the bacillus may result in anesthesia and deformities of the hands and feet and lagophthalmos of the eyes. In lepromatous HD there may be iritis, direct invasion of the anterior part of the eye by the bacilli, and in males, it may cause testicular atrophy and gynecomastia. A complete physical assessment of the patient is necessary.

In most people, resistance develops to infection with *M. leprae*. The body's defenses kill the invading bacteria, or contain the infection so disease does not develop. In persons with limited or no resistance to the disease, the bacteria grow slowly, eventually leading to the appearance of symptoms. Presence of the bacteria will be demonstrated with skin smears or biopsy.

Hypo- or hyper-pigmented, flat or raised lesions appear, which are insensitive to light touch. These are most commonly found on the buttocks, thighs, trunk, and lateral aspect of the upper and lower extremities. There may be anhidrosis, loss of hair on the skin, and changes in skin texture. The earlobes may be swollen and pendulous.

Patients may experience inflammation of the eyes, excessive or decreased tearing, loss of corneal sensation and lateral eyebrows, and incomplete closure of the eyelids.

Muscle strength of the hands and feet may be affected. There may be dryness, decreased sensation, muscle atrophy, deformity such as clawing of fingers or toes, wounds, and ulcers. Male patients may have painful, swollen testicles or gynecomastia.

Peripheral nerves may be enlarged or tender. The ulnar, median, radial cutaneous, posterior tibial, peroneal, and greater auricular are most commonly affected. Some patients complain of pain in the extremities, and a burning sensation in the soles of the feet. Abnormal nerves will feel sclerosed.

Effects of Hansen's Disease on Peripheral Nerves

Disability and deformity in HD are primarily due to nerve damage. The damage is caused by bacilli in the perineurium, the influx of inflammatory cells, the sheer bulk of bacillary material in both Schwann cells and invading macrophages, and by fibrosis occurring in the inflamed nerve. In addition to sensory loss or muscle paralysis, other effects of this denervation are anhidrosis and decreased oil production in the skin. This causes the skin to become dry and inelastic, leading to difficulties in healing when trauma occurs. The functionally important nerves most commonly damaged are the facial, ulnar, median, radial, peroneal, and posterior tibial.

Most of the disability and deformity in HD is secondary due to repetitive trauma and infection of insensitive areas. These secondary effects of nerve damage are preventable. Persons with normal sensation rely on the sense of pain to warn them of possible trauma and are able to prevent serious injury. Those who have lost sensation have to learn other methods to protect insensitive areas from injury. The specific psychological effects associated with a significant loss of sensation also need to be considered.

The Peripheral Nerves

- The Facial Nerve - The orbicularis muscle, innervated by the facial nerve, is sometimes affected in persons with HD. Damage to this nerve results in lagophthalmos, exposing the cornea to possible damage, especially during sleep. Loss of corneal sensation will compound the problem because the blink reflex may be compromised.

- Ulnar, Median, and Radial Nerves - Most commonly, the ulnar nerve is involved at the elbow and the wrist, and the median nerve is damaged just proximal to the wrist and in the carpal tunnel. Early signs are dryness of the hands, callus formation, and signs of trauma due to insensitivity, such as burns. The result of severe nerve damage will be atrophy of the intrinsic muscles of the hand, including the hypothenar and thenar areas. There may be clawing of the digits and weakness of pinch (ulnar) loss of opposition of the thumb (median), and wrist drop (radial).
- Peroneal and Posterior Tibial Nerve - Damage to the peroneal nerve causes anesthesia in the lateral aspect of the lower extremities and dorsum of the feet. The motor deficit is in the peroneal muscles and dorsiflexors of the foot; the earliest sign is difficulty in dorsiflexion or eversion of the foot against pressure. The result of a full motor deficit in this area is foot drop. Damage to the posterior tibial nerve will result in anesthesia of the plantar surface of the foot, and claw toes. Observe for a high-stepping, inverted gait, callus formation on the toes and plantar surface, and erythematous or warm pressure areas on the foot.
- Sensory Testing of Hands and Feet - Sensory testing of hands and feet with nylon filament should be done at the time of diagnosis and periodically during treatment to detect evidence of nerve damage at the earliest possible stages. This is an important part of disability prevention. Early detection of problems makes it possible to take steps which can prevent further nerve damage.

Surgery

Most patients with IID do not require any surgery but there are occasional situations in which the following surgical procedures may assist in therapy or rehabilitation:

- Incision and Drainage
- Tendon transfer procedure
- Surgical release of nerves
- Procedures for stabilization of Charcot foot.

Silent Neuritis

There are some patients who have no signs of reaction or nerve pain, but continue to have progressive sensory or motor loss in hands or feet. Such patients need to be assessed to determine that they are receiving appropriate chemotherapy since noncompliance with drug intake could contribute to this problem. However, there are still some patients who are taking their medications regularly and still have deteriorating nerve function. The cause of this deterioration is not known, but some of these patients will have improvement if they receive steroid treatment. If the loss of function has been 3 months or less, they should be given a course of steroids in the dose range for reactions. If the loss has been present for longer than 3 months the chance of recovery is diminished. Therefore, it is important to monitor all patients under treatment for any changes in nerve function and treat accordingly.

HD and Pregnancy

A female with HD who is pregnant is rare in the U.S., but a few cases occur each year. The majority of these pregnancies are uneventful as far as HD is concerned, but there are a number of potential problems and risks that should be considered when advising female HD patients of childbearing age, and when managing patients who are already pregnant and have HD.

All female patients of childbearing age should be advised to avoid pregnancy during early stages of the disease, at least until MDT has been completed and preferably until the disease is completely inactive. The postponement of pregnancy is especially important for patients who have evidence of reaction or neuritis since these problems will be exacerbated during pregnancy and the postpartum period. There may also be a very small risk of transmission of the disease from mother to infant in those cases where the pregnancy occurs before treatment or early in the course of treatment.

There are alterations in the immune response during all pregnancies, causing a depression of the cell-mediated immune system. This immune suppression during pregnancy and its recovery in the postpartum period appears to play a role in the clinical manifestations of HD in women. It is common for the first symptoms of HD in young women to occur during pregnancy or the postpartum period. An increased risk of relapse during pregnancy has also been reported.

ENL is more common during pregnancy when the CMI is depressed, while reversal reaction is more common during the postpartum period when the CMI is recovering.

The risk of reactions or neuritis during pregnancy will vary considerably with the type of disease and the amount of treatment a patient has received prior to the pregnancy. If a reaction occurs during a pregnancy, it should be managed as in non-pregnant patients with the use of prednisone sufficient to control the reaction and prevent nerve damage. Thalidomide cannot be used.

For patients who are or become pregnant during the early stages of the disease, chemotherapy should generally continue during pregnancy with some modification of the regimens in some cases. We avoid the use of rifampin during pregnancy if possible. Dapsone can be continued throughout the pregnancy.

Patients who have had HD sometime in the past, who have been adequately treated, and whose disease is now completely inactive, can be expected to have essentially normal pregnancies. There is no risk of the mother transmitting the disease to infants in such cases.

HD and Children

HD in children is uncommon in the U.S., but does occur and is usually indeterminate or tuberculoid type disease. It is usually a benign disease with very few deformities reported. Management of the disease is generally the same as for adults except for the adjustment of drug dosages to be determined by the physician. Transmission of HD to children should not occur after the adult patient starts on treatment that includes rifampin. Preventive treatment is not generally recommended for child contacts. The presence of new cases in children usually indicates that HD is still being transmitted in the general population.

Testicular HD

Direct invasion of the testicles probably occurs in most cases of Borderline and Lepromatous disease, although testicular dysfunction is most common in Lepromatous disease. The testicles are a cool part of the body and are preferentially affected. If HD is not treated early, there is progressive destruction of testicular tissue and eventually testicular atrophy with sterility and a decrease in testosterone production.

Gynecomastia usually develops relatively late and is an indication of advanced disease. Acute orchitis may develop during ENL and may be an indication for prednisone therapy. Testicular atrophy is usually permanent. After testicular function is destroyed, the only treatment is testosterone replacement. This does not restore fertility but is helpful in restoring sexual potency. Injectables are the preferred route for replacement therapy. Oral androgens are not recommended for long-term therapy because of potential liver toxicity.

DIAGNOSTIC CRITERIA

In the U.S., HD is diagnosed through biopsy of a skin lesion associated with loss of sensation.

SCHEDULE OF SERVICES

I. New Patient

- A. Patient Interview
- B. HD Monitors
- C. Medical Assessment
- D. Biopsy
- E. Skin Smears (optional)
- F. Baseline laboratory studies
- G. Hand and Foot Screens
- H. HD Surveillance Form
- I. HD Patient Education

II. Follow-Up Visit

- A. Patient Interview
- B. HD Monitors
- C. Medical Assessment
- D. Laboratory monitoring (See Lab Monitoring below for schedule)
- E. Annual biopsy is recommended
- F. Skin Smears annually (optional)
- G. Hand and Foot Screens (See Frequency of Performance in Appendix)
- H. Patient Education every clinic visit

PATIENT ASSESSMENT

I. Patient Interview

- A. Family History of HD
- B. Presenting Symptoms
 1. No pain reported with injuries such as cuts or burns
 2. Recurrent nosebleeds
 3. Chronic nasal congestion
 4. Burning sensation on soles of feet or hands
 5. Painful / tender peripheral nerves
- C. Psychological considerations
 1. Stigma/myths
 2. Living with the diagnosis-family, friends, boss, colleagues
 3. Common concerns-cause, treatment, contagiousness, sexual relations, deformities

II. Physical Assessment

- A. Skin-It is important to perform a complete examination of the skin in good light. Hypo-pigmented or hyper-pigmented flat or raised lesions may be found on the face, trunk, extremities, buttocks, or thighs. Absence of sweating, hair loss, or changes in texture of the skin may also be present. Ask male patients about pain or swelling of the testicles and examine for erythematous nodules.
- B. Eyes-Examine the eyes for inflammation, incomplete closure of the eyelids, and pupil size. In patients with borderline lepromatous disease, an ophthalmological exam should be done to rule out eye involvement.
- C. Nerves-A peripheral nerve assessment should be done to determine if nerves are enlarged or tender (See Appendix). The ulnar, median, radial cutaneous, posterior tibial, and peroneal nerves are commonly affected. In patients with anesthesia of the hands or feet, ulcerations, muscle atrophy, or deformity may be present. A common complaint is pain in the extremities and a burning sensation in the soles of the feet.
- D. Hands and Feet-Hands and feet should be examined for dryness, diminished sensation, muscle weakness or muscle atrophy, wounds, and ulcers.
- E. HD Monitors-The purpose of this exam is to perform a visual inspection and assessment of motor function of the eyes, hands, and feet of a patient with HD. It is an excellent venue for teaching patients about the prevention of complications. (See Appendix for procedure)

LABORATORY MONITORING

I. Recommended Laboratory Tests and Frequency

	Initial visit	2 nd visit (1-2 months)	3 m	6 m	12 m	18 m	24 m
CBC + platelets	X	X	X	X	X	X	X
AST	X		X	X	X	X	X
ALT	X		X	X	X	X	X
CRP	X	X	X	X	X	X	X
BUN	X						
Creatinine	X						
Bilirubin	X						
G6PD	X						
Hepatitis B*							
Hepatitis C*							

*Screen for these or other co-morbidities if patient requires prednisone for reaction

II. Other tests

A. UA should be done annually with these studies for all patients.

B. PCR Assay (Polymerase Chain Reaction)

In a non-endemic population, the sensitivity and specificity of PCR assay recommend its use primarily to identify *M.leprae* when acid-fast organisms are discernible but atypical clinical or histopathologic features are obscuring the diagnosis. The Assay is not highly informative when acid-fast bacilli are not detectable by light microscopy. (Am J Clin Pathol 1998; 109:642-646) To further determine whether this Assay would be clinically appropriate, contact Dr. David Scollard, Chief, Clinical Branch NHDP, at 225-756-3713.

TREATMENT OF HD IN THE U.S.

I. Clinical Spectrum of HD

The clinical features of HD cover a wide range, from a single hypo-pigmented skin macule to generalized disease. Wide differences are seen in the pathological features, immunological status, treatment required, and types of complications that develop. For treatment purposes, the NHDP uses the WHO two-group classification, into which the Ridley-Jopling five-group classification is incorporated.

A. Indeterminate (I) HD is the earliest stage of disease, and consists of one or two vague hypo-pigmented macules, slightly dry in texture, with anhidrosis, and generally, no *M.leprae* in the lesion. Over half of these cases resolve without treatment, others progress eventually into one of the other forms of HD.

- B. Tuberculoid (TT) is limited disease with few, well-defined hypo-pigmented skin lesions which have marked sensory loss. Loss of hair in the lesion is common and there is often central healing. Without treatment, lesions may enlarge slowly, or self-heal. M.leprae are few or hard to find, but peripheral nerve involvement is common, leading to severe disabilities if nerve damage occurs.
- C. Borderline (BT, BB, BL) disease has features of both the tuberculoid and lepromatous types of HD. Skin lesions occur in small and large sizes and may be hypo- or hyper-pigmented. These lesions may or may not be anesthetic.
- D. Lepromatous (LL) type disease is characterized by lesions which are numerous, small, and symmetrically distributed. They may be hypo- or hyper-pigmented. The skin, nerves, bones, eyes, and nasal area are most often affected; however, all organs may become involved. There may be elongated ear lobes with partial or complete loss of the eyebrows, and anhidrosis of some parts of the body.

II. Treatment

Treatment of HD involves more than simply prescribing medication. Good health education at the time of diagnosis and during the course of treatment will make it more likely that the patient will have a better outcome. Thus, an important part of the management of HD is providing accurate information to patients and families regarding the expected course and prognosis of the disease.

A. Recommended Treatment Regimens

Following are the general NHDP recommendations for the treatment of persons with HD in the U.S. NHDP recommendations are for daily rifampin, and for longer duration of treatment than the WHO recommendations. Treatment that is more intensive and of longer duration is medically preferable.

Treatment guidelines for immunologically competent individuals, (e.g. those without immunodeficiency, immunosuppression, prolonged corticosteroid use, etc.) are as follows:

Adults		
Tuberculoid (TT & BT) (WHO classification Paucibacillary, "PB")		
Agent	Dose	Duration
Dapsone	100 mg daily	12 months, and <u>then therapy discontinued</u>
Rifampicin	600 mg daily	

Adults		
Lepromatous (LL, BL, BB) (WHO classification Multibacillary, "MB")		
Agent	Dose	Duration ^a
Dapsone	100 mg daily	24 months, and <u>then therapy discontinued</u>
Rifampicin	600 mg daily	
Clofazimine ^b	50 mg daily	

For immunologically compromised patients, these protocols may be modified, and consultation with the NHDP is recommended.

- a. The recommended durations of treatment are sufficient, even though large numbers of dead bacilli may remain in the tissues for several years, before they are eliminated by physiological processes. There is no evidence that additional, prolonged treatment hastens the elimination of these dead organisms.
- b. Clofazimine, used for decades to treat HD around the world, is no longer available on the open market. Because it is no longer distributed commercially, the only way we can obtain the drug in the U.S. is to once again treat it as an investigational new drug (IND). The NHDP holds this IND for its use in treating HD in the U.S.

B. In order for physicians to obtain the drug for treating HD, they will have to be registered as an investigator under the NHDP IND. This will require submitting a signed FDA form 1572 and a curriculum vitae to the NHDP. A packet of information including the form 1572 as well as consent forms, etc., will be provided. An Institutional Review Board (IRB) of the Centers for Disease Control has agreed to act as the central IRB for the use of Clofazimine for Hansen's Disease, so that individual physicians do not need to arrange this themselves. For further information, or to request investigator status to use Clofazimine, please call the NHDP at 1-800-642-2477.

C. ALTERNATIVE ANTI-MICROBIAL AGENTS

1. Minocycline, 100 mg daily, can be used as a substitute for Dapsone in individuals who do not tolerate this drug. It can also be used instead of Clofazimine, although evidence of the efficacy of its anti-inflammatory activity against Type 2 reactions is not as substantial as the evidence for Clofazimine.
 2. Clarithromycin, 500 mg daily is also effective against *M. leprae*, and can be used as a substitute for any of the other drugs in a multiple drug regimen.
 3. Ofloxacin, 400 mg daily, may also be used in place of Clofazimine, for adults. This is not recommended for children.
- D. In the United States, the occurrence of leprosy in children is rare. We strongly recommend contacting the NHDP for management of leprosy in children; the following are general guidelines.

Treatment for children

Tuberculoid (TT & BT) (WHO Paucibacillary, "PB")

Agent	Dose	Duration
Dapsone	1 mg/ Kg daily	12 months, and <u>then therapy discontinued</u>
Rifampicin	10-20 mg/ Kg daily (not > 600)	

Treatment for children

Lepromatous (LL, BL, BB) (WHO Multibacillary, "MB")

Agent	Dose	Duration
Dapsone	1 mg/ Kg daily	24 months, and <u>then therapy discontinued</u>
Rifampicin	10-20 mg/ Kg daily (not > 600)	
Clofazimine ^c	1.0 mg/Kg daily ^c	

- c. As there is no formulation less than 50 mg, and the capsule should never be cut open, alternate day dosing may be used at 2 mg/kg.

E. Common Side-effects of HD medications

1. Dapsone
 - a. Contraindications-prior allergy to dapsone, 6PD deficiency, breast-Feeding
 - b. Side effects-hemolysis
2. Rifampin
 - a. Contraindications-prior allergy to rifampin
 - b. Side effects-abnormal liver function, thrombocytopenia, drug interactions with oral contraceptives and anticoagulants, reddish discoloration of urine, stools, saliva, tears, and sweat

3. Clofazimine
 - a. Contraindications-none indicated
 - b. Side effects-discoloration of skin, diarrhea, abdominal pain, and less commonly, bowel obstruction

On November 1, 2004, Novartis Pharmaceuticals Corporation ceased distribution of lamprone (clofazimine) in the U.S. through its usual distribution channels. It is only available now through Investigational New Drug (IND) protocol. To receive clofazimine for treatment of HD, you must be enrolled as an investigator under the IND held by CDC. To enroll, contact Catherine Crnko at:

Catherine Crnko, Administrative Officer
National Hansen's Disease Programs
ccrnko@hrsa.gov
1770 Physician Park Drive
Baton Rouge, LA 70816
Phone: (225) 756-3709, Fax (225) 756-3819

****Clofazimine** has been safely used in children and pregnant women for years. For questions regarding this process, please call Barbara Stryjewska, MD, Principal Investigator/Sponsor, at 1-800-642-2477.

New Drugs

Several new drugs have been studied and undergone small clinical trials. Larger clinical trials are now in progress. The most promising of these are ofloxacin, minocycline, and clarithromycin. Although these drugs are already marketed and available for other uses, at present there is only limited information on the use of these drugs in the treatment of HD. Therefore, they are not recommended as routine or first line anti-leprosy drugs at present. The main indication for their use at present would be in patients with drug intolerance for the currently recommended drugs or cases of documented drug resistance. It is important to make the best use of the drugs that are available to avoid increasing the problem of drug resistance.

D. Follow-Up after Completion of Treatment

Clinical examinations should be done at the following intervals:

1. Paucibacillary (PB) - Annually for three years
2. Multibacillary (MB)
 - a. Every six months for two years
 - b. Annually for eight years
3. Skin biopsies are recommended annually

REACTIONS IN HD

Although *M. leprae* is almost non-toxic, some patients develop acute hypersensitivity "reactions" to the organism. These are known as "lepra reactions". Reports of the frequency of reactions indicate that 25% to 50% of all HD patients will have a reaction sometime during the course of the disease. There are no predictors of which patients will develop reaction, other than patients with tuberculoid disease do not have reactive episodes. Reactions are also less frequent in patients taking clofazimine. There are two types of reaction, Reversal Reaction or Type I Reaction, and Erythema Nodosum Leprosum, or ENL, which is Type II Reaction. For guidance on management of reaction, call the NHDP at 1-800-642-2477.

I. Symptoms of Reaction

- A. Neuritis-Enlarged or tender peripheral nerves; changes in sensation or strength
- B. Muscle weakness
- C. Tender, painful, erythematous nodules which may ulcerate
- D. Development of new lesions
- E. Malaise
- F. Fever-low-grade to moderate
- G. Red, painful eyes
- H. Orchitis in patients with multibacillary disease
- I. Edema of hands and feet

II. Treatment of Reactions

Reactions are a major cause of nerve damage, so the focus of management should be on the prevention of nerve damage. Damage to the nerves is caused by the tissue response within the nerves to intraneural *M. leprae* and is similar to the process seen in the skin. In untreated HD without reaction, nerve damage is more insidious, while in reaction, nerves may be damaged more rapidly. Skin reactions and acute neuritis often occur together. Antibacterial treatment should be continued at full dosage.

Patients with mild reaction may be treated symptomatically. Those with moderate to severe reaction may require steroids, thalidomide, or clofazimine. Patients with severe reaction, especially those with evidence of nerve damage, require treatment with corticosteroids. Some patients may require high doses of corticosteroids to control reaction and prevent nerve damage. They should have a baseline Bone Density test prior to initiating extended therapy with high doses of corticosteroids.

A. Treatment with steroids

1. Contraindications

- a. Inadequately treated infection
- b. Situation where medically supervised stoppage of medication is not possible

- c. Prolonged usage without close medical supervision
- 2. Side effects
 - a. Weight gain or potassium loss
 - b. New infection or exposure to an infectious person
 - c. Poor response to some immunizations
 - d. Interaction with laboratory or medical procedures such as blood sugar and TB skin tests
 - e. Withdrawal effects

- B. Thalidomide is very effective in controlling ENL, and is the drug of first choice if not contraindicated. This drug is very teratogenic and causes severe birth defects if taken by women during pregnancy.

In the U.S., Thalidomide is available to the prescribing physician and the dispensing pharmacist by registering with Celgene's System for Thalidomide Education and Prescribing Safety (STEPS) program. Male patients taking this medication must use prophylactics during sexual intercourse. Pregnancy tests at regular intervals are required for female patients of childbearing age.

- 1. Contraindications
 - a. Pregnancy
 - b. No unauthorized person may take this medication
- 2. Side effects
 - a. Fetal developmental defects
 - b. Constipation
 - c. Drowsiness
 - d. Dizziness

- C. Clofazimine can be given in a dose of 300mg daily for four to six weeks, reduced to 200 mg daily for several months, and then reduced to 100mg daily. The addition of clofazimine at these doses will usually make it possible to reduce the dose of steroids required, but not eliminate them entirely. Clofazimine is not quick acting and it may take six weeks or more for the full effect on the reaction to be noted. Patients receiving larger doses of clofazimine will have more severe skin pigmentation and more frequent gastro-intestinal side effects.

When the patient has required no steroids for approximately three months, the dosage of clofazimine can be reduced to 50mg daily. If clofazimine is not required for antibacterial treatment, it can be discontinued when no steroids have been required for an additional three months.

For consultation on the treatment of reaction, call the NHDP at 1-800-642-2477.

REHABILITATION SERVICES

I. Hand and Foot Rehabilitation Services

An efficient and comprehensive rehabilitation program in the management of insensitve limbs shall incorporate physical therapy, occupational therapy, pedorthics, and patient education. Rehabilitation goals aimed at minimizing loss of function, ulceration, amputation, and ultimate disability, can be satisfactorily achieved utilizing the following interdisciplinary rehabilitation practices: hand and foot care, exercise, wound care, splinting, casting, recommending assistive devices, follow-up therapy for HD orthopedic procedures, and in collaboration with the medical staff, identifying candidates for reconstructive surgery.

Disability prevention is promoted by the visual inspection of the hands, and feet of the patient at each encounter. If the hand or foot requires further evaluation, a hand or foot screen and palpation of the nerves shall be done. (See appendix, HD Manual for procedures.)

For patients scheduled to receive care at the NHDP in Baton Rouge, the Ambulatory Care therapist coordinates care with the NHDP therapists. Preoperative casting, wound care and postoperative rehabilitation provided by the therapist in the Ambulatory Care setting decreases the length of stay required for care at the NHDP.

A. Occupational Therapy

1. **Hand Screens** – These are a means of assessing the HD patient's risk category for hand problems, and for developing a care plan for their prevention and treatment.
2. The sensory testing device used with the Hand Screen is a set of five (5) calibrated nylon filaments mounted on a small rod, which measure levels of cutaneous touch and pressure on a scale of 2.83 to 6.65. The normal threshold level is 2.83.

B. Physical Therapy

1. **Foot Screens** – The Foot Screen has been proven to accurately identify patients who are at risk of developing deformities as a result of insensitivity, and also provides a baseline for determining the extent of foot disabilities.
2. The sensory testing device used with the Foot Screen is a nylon filament mounted on a holder designed to deliver a 10 gram force when properly applied. Our research has shown that a patient can feel the 10 gram filament in the selected sites will not develop ulcers.

(3) Frequency of Performance:

1. Hand and foot screens shall be done for new patients at the time of diagnosis, and on a quarterly basis as patients are scheduled for laboratory monitoring during chemotherapy
2. Screens should also be performed as clinically necessary on any patient complaining of muscle weakness, decrease in sensation, or change in function

The hand and foot filament sets for the Ambulatory Care Clinics may be obtained by calling 1-800-642-2477. The NHDP Rehabilitation Department staff are also available for consultation as necessary.

CONSULTANT SERVICES

- I. Due to the multi-faceted aspects of this disease, patients may need referral to the following ancillary medical services for complications. Not all consultant services will be needed in every case and some will be indicated only rarely. Consultation with NHDP staff is also available by calling 1-800-642-2477.
 - A. Physical Therapy
 - B. Occupational Therapy
 - C. Podiatry
 - D. Orthotics
 - E. Orthopedics
 - F. Ophthalmology
 - G. ENT
- II. Consultation with NHDP staff is also available by calling 1-800-642-2477.

CONTACT FOLLOW-UP

In the U.S., a Hansen's disease contact is identified as a person living in the same household with a new patient in the three year period prior to the diagnosis and the beginning of treatment. These contacts should be examined as follows:

- I. Contact examination
 - A. Exam of the entire skin
 - B. Nerve function assessment of the peripheral nerves, focusing primarily on the eyes, hands, and feet (See Appendix).
 - C. The contact exam should also include patient education on the disease, and what symptoms a contact should report to the health care provider.
 - D. An individual with symptoms of HD may be referred to one of the Outpatient HD Clinics or to the NHDP by physicians or healthcare agencies. These persons will be provided with the services required to rule out the diagnosis of HD as described above.

II. Follow-Up of Contacts

- A. Contacts of a paucibacillary case with a negative initial exam do not need follow-up as long as the patient has been educated about the symptoms of HD.
- B. In contacts of a multibacillary case, exams should be done annually for five years, including patient education about the disease and its symptoms
- C. The NHDP does not recommend chemoprophylaxis with dapsone or any other drug for contacts of patients.

REPORTING REQUIREMENTS

The NHDP maintains a National HD Registry in the U.S. for all patients diagnosed with Hansen's disease.. A Hansen's Disease Surveillance Form is required on all newly-diagnosed patients. The Form can be found on the NHDP website, www.hrsa.gov/hansens, and should be sent to NHDP as soon as the diagnosis is confirmed. The HD Surveillance Form should be mailed or faxed to:

NHDP
ATTN: Medical Records,
1770 Physicians Park Drive,
Baton Rouge, LA 70816
Fax: 225-756-3706

PATIENT EDUCATION

Appropriate treatment of a stigmatizing disease like HD involves more than merely prescribing medications. Many patients fear they will become severely disabled and will infect their families. They also fear social isolation if others become aware of their diagnosis. Awareness of these patient concerns at the time of diagnosis and during the course of treatment will more likely ensure patient compliance with treatment and achieve its objective, which is the prevention of deformity and disability.

REFERRALS TO NHDP

Physicians at the NHDP may authorize a referral to the NHDP on a case-by-case basis.

AMBULATORY CARE PROGRAM

The Ambulatory Care Program provides HD outpatient care through Outpatient Hansen's Disease Clinics located where most of the patients live in the U.S. and Puerto Rico. Services provided by these Clinics include diagnosis and treatment of HD and related conditions, laboratory monitoring, consultant services, patient and community education.

PRIVATE PHYSICIAN PROGRAM

HD medications can be provided to patients living in an area not served by an HD clinic through the NHDP. Their private physician can order the HD medications (dapsone, rifampin, clofazimine) from the NHDP at no charge to the patient. Consultant and biopsy processing services are also provided to the physician.

RESOURCES

- I. Resources available from the NHDP for HD are:
 - A. Consultation on treatment and management guidelines
 - B. Medications for HD: dapsone, rifampin, clofazimine
 - C. Processing biopsies for histopathology
 - D. HD and Foot Seminars for Physicians, Nurses, Occupational Therapists, Physical Therapists, Orthotists, and Podiatrists
 - E. NHDP Website-www.hrsa.gov/hansensdisease

Information regarding these services is available from the NHDP, 1770 Physicians Park Drive, Baton Rouge, LA, 70816, Phone: 800-642-2477; Fax: 225-756-3806.

II. Other Resources

- A. American Leprosy Missions
1 ALM Way
Greenville, SC 29601
Phone: 800-543-3131
- B. IDEA (International Association for Integration, Dignity,
And Economic Advancement)
U.S. Headquarters
P.O. Box 651
32 Fall Street-Suite A
Seneca Falls, NY 13148
Phone: 315-568-5838 Fax: 315-568-5891
E-mail: alaw@idealeprosydignity.org
- C. Support for People with Hansen's Disease/Leprosy
Phone: 1-866-637-1525
Website: <http://www.hansensdisease.org>
E-mail: niholmes@hansensdisease.org

NHDP
Rev. 7/2012

FORMS AND PROCEDURES

APPENDIX A:	Hansen's Disease Monitors
APPENDIX B:	Peripheral Nerves
APPENDIX	Skin Biopsy Protocol for Submitting Specimens
APPENDIX D:	Skin Smears Skin Smears for Acid-Fast Bacilli Procedure for Obtaining Smears Skin Smear/Biopsy Chart Staining of Skin Smears Microscopic Examination of Skin Smears
APPENDIX E:	Hand and Foot Screens Standards for Performance of the Hand Screen Hand Screen Instructions Hand Screen Record Standards for Performance of the Foot Screen Foot Screen Encounter Form Foot Screen Record WHO Grading of Disabilities Hands and Feet
APPENDIX F:	Hansen's Disease Medication Chart English Spanish
APPENDIX G:	Surveillance Form Instructions for Surveillance Form HD Surveillance Form
APPENDIX H:	Hansen's Disease Outpatient Clinic Listing
APPENDIX I:	Hansen's Disease Outpatient Clinic Listing

APPENDIX

Hansen's Disease Monitors

The Hansen's disease (HD) monitors are a system of assessment which includes a visual inspection and assessment of motor function of the eyes, hands, and feet of a patient with HD. These procedures can be used to teach patients about prevention of complications.

1. Visual Inspection

a. Eyes

1. Examine the eyes for inflammation
2. Check the pupil size, shape, and reaction to light
3. Ask the patient to close their eyes and check for incomplete closure

b. Hands

1. Inspect the palms and dorsum of the hands for dry skin
2. Check for muscle atrophy and injuries

c. Feet

1. Inspect for dry skin, erythema, calluses, and injuries
2. Check socks and shoe wear for signs of drainage from ulcers or injuries

2. Motor Function Assessment

These assessments should be done with the application of resistance by the examiner, otherwise early signs of weakness may be missed. (See attachment)

3. Shoewear Assessment for Insensitive Feet

- a. Extra-depth shoes with removable insoles
- b. Rounded or square toe box
- c. Leather upper
- d. A half-inch length beyond longest toe
- e. No seams at the toe
- f. Soft wedge sole

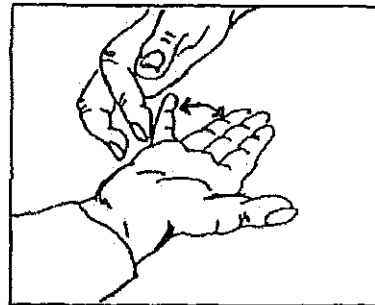
A patient with a positive eye exam should be evaluated by an ophthalmologist; hand and foot problems need follow-up with a hand or foot screen and referred as necessary.

HANSEN'S DISEASE MONITORS

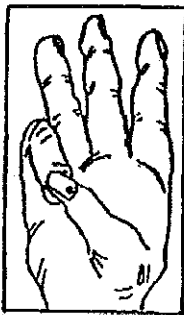
FACIAL NERVE
Have patient close eyes as in sleep. Look for incomplete closure of eyelids.



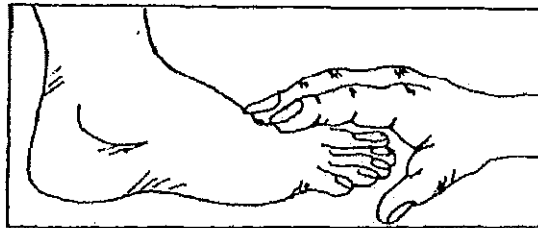
ULNAR NERVE
Have patient abduct little finger against resistance applied by examiner.



MEDIAN & ULNAR NERVES
Have patient approximate little finger and thumb with hand in prone position.



PERONEAL NERVE
Ask the patient to bring foot up. Apply resistance when foot is up. There will be weakness or paralysis when patient is unable to resist the downward movement that is applied to the foot.



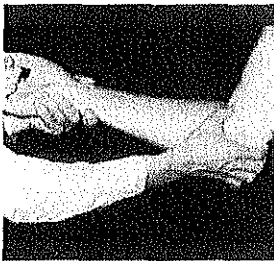
These assessments are to be done with application of resistance by examiner; otherwise early signs of weakness may be missed. A patient with a positive eye exam should be evaluated by an ophthalmologist. Positive hand or foot assessments shall be further evaluated through a hand or foot screen and referred.

Appendix B

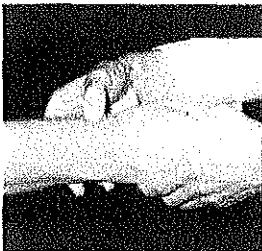
PERIPHERAL NERVES



Greater auricular-with the patient's head turned to one side, palpate the nerve as it stretches across the sternomastoid muscle.



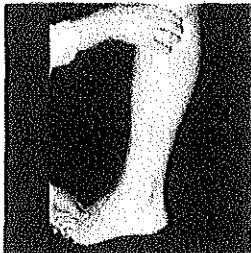
Ulnar-palpate above the ulnar groove.



Radial cutaneous-palpate at the lateral border of the radius proximal to the wrist joint.



Posterior tibial-posteriorly and inferiorly to the medial malleolus.



Common peroneal-palpate the popliteal fossa just medial to the biceps femoris tendon, and around the neck of the fibula.

SKIN BIOPSY

A proper site is the single most important factor in the skin biopsy to be evaluated for leprosy. The pathologist will be unable to make a definite diagnosis if bacilli cannot be demonstrated by means of the biopsy. A general rule is that the biopsy should be taken entirely within the lesion, preferably from the active margin if there is one; this is especially important in the non-lepromatous forms of leprosy. There is no necessity to include any normal tissue in the biopsy. When no definite lesion can be found, the site for biopsy should be guided by information from skin scrapings and clinical findings such as decreased sensation and decreased sweating.

The skin biopsy should be made with a biopsy punch or by surgical excision. In all instances, the biopsy should be deep enough to include subcutaneous fat; this depth of biopsy is very important, for often the most prominently involved nerves will be found in the upper portion of the subcutaneous tissue. A 4 mm or larger biopsy punch should be used; a 2 or 3 mm punch biopsy can be made on the face, if necessary. Surgical excision is made 1 cm by 3 mm, with a cold knife; removal of specimens by cautery is to be entirely avoided. A proper fixative should be employed for specimen fixation and transfer; 10% neutral buffered formalin is used routinely. At least five volumes of fixative per volume of tissue should be used.

For his to pathological consultation, at no charge, mail specimens in 10% neutral buffered formalin to:

National Hansen=s Disease Programs
Attention: Clinical Laboratory
1770 Physicians Park Drive
Baton Rouge, Louisiana 70816

For questions regarding these procedures, please call 1-800-642-2477.

PROTOCOL FOR SUBMITTING SPECIMENS FOR HISTOLOGICAL EVALUATION OF HANSEN'S DISEASE

National Hansen's Disease Programs
Baton Rouge, Louisiana

The following are the requirements needed before sending a biopsy for routine histological evaluation:

1. A biopsy collected with a 4 – 5 mm punch (2 mm if on face) or surgical excision, which should be deep enough to include subcutaneous fat. This depth is important because often the most prominently involved nerves will be found in the upper portion of the subcutaneous fat. As a general rule, the biopsy should be taken entirely within the lesion, preferably from the active margin if there is one.
2. Place in 10% buffered formalin, at least 5 volumes of fixative per volume of tissue. Label container with patient's name and biopsy site.
3. A brief clinical history including number of lesions, changes in sensation, previous diagnosis and present clinical impressions.
4. The patient's name, sex, race and social security number if available.
5. The patient's date of birth.

6. The submitting doctor's name and the address where the report is to be sent.
7. Send biopsy in leak-proof container.

The following specimens may also be submitted for evaluation (listed in order of preference):

1. Paraffin blocks.
2. Slides of unstained sections - preferably at least 4 slides.
3. Stained slides to include H&E and Fite.

Specimens should be placed in protected mailing containers such as screw-cap cardboard cylinders or padded mailing envelopes to prevent damage.

Specimens are then sent to:

National Hansen's Disease Programs
Clinical Laboratory
1770 Physicians Park Drive
Baton Rouge, LA 70816
Attn: George Reed or Steve Keas
Phone: 1-800-642-2477

SKIN SMEARS FOR ACID-FAST BACILLI

PURPOSE:

The skin smear is a valuable, cost-effective tool in the routine management of the Hansen=s disease patient. The smear is a means of estimating the number of acid-fast bacteria present, reported as the bacterial index (BI), and is important in determining the type and severity of disease as well as assessing the response to treatment.

GENERAL:

1. Initial skin smears are usually taken from 6 Aroutine sites@ (both earlobes, elbows, and knees) as well as several typical lesions from the patient.

Repeat smears are obtained from 3 to 4 of the most active sites previously tested to evaluate progress.

2. The time interval between repeat smears is determined by the physician but in general, annual smears are adequate for monitoring response to treatment and during the follow-up period to detect any evidence of relapse.
3. They may be sent in protective mailers to:

National Hansen=s Disease Programs
Attention: Clinical Laboratory - Skin Smears
1770 Physicians Park Drive
Baton Rouge, Louisiana 70816
Phone: (225) 756-3733


PROCEDURE FOR OBTAINING SMEARS:


1. Universal precautions should be observed in obtaining skin smears.
2. All microscopic slides on which skin smears are made should be precleaned in 70% alcohol, acetone, or alcohol-acetone to remove amorphous debris. The slides are wiped dry with a clean hand towel. Blades that are used in smear taking are likewise cleaned.
3. The skin is cleansed with 70% alcohol and air dried or wiped dry with cotton. (Zepharin tends to make the skin too slippery and is not recommended.)
4. A fold of skin is made relatively avascular by pinching. If the skin cannot be grasped by pinching, it can be compressed. A surgeon's glove may aid in grasping.
5. Local anesthesia is generally unnecessary. (If there is not adequate decrease in sensation,


obtain local anesthesia with 1% Xylocaine, or Ethyl Chloride spray can be carefully applied.) The compression of the skin by pinching aids in the anesthesia.

6. An incision 3-5 mm long and 2-3 mm deep is made with an alcohol-cleansed single-edge razor blade or a scalpel with a #15 Bard-Parker blade may also be used. **The blade or scalpel should be used for only one site and then discarded.** Mild pressure to maintain relative avascularity is continuously applied to the area until an adequate smear has been obtained.
7. A small amount of blood does not interfere with the reading, but large amounts should be avoided and can usually be controlled by the amount of pressure of the pinch. If excessive bleeding occurs, it can be wiped away with a cotton swab.
8. After the incision is made, and before the blade is withdrawn, the inner surface of the wound is scraped with the blade held at a right angle to the incision. Upon scraping, tissue fluid and dermal tissue are obtained.
9. The material is transferred to the cleaned microscope slide. A moderately thick smear, with a visible uniform opacity is made. The smear is made in a circular manner on the slide, **no larger than a pencil eraser (5-7 mm) in diameter**, beginning peripherally and ending in the center, leaving a central "button" (2-4 mm) which can be easily focused upon with the microscope. Slides should be properly labeled as shown in the sample diagram for 3 routine sites.

Name	
1. R -knee	
2. R-elbow	
3. R - ear	
Date	

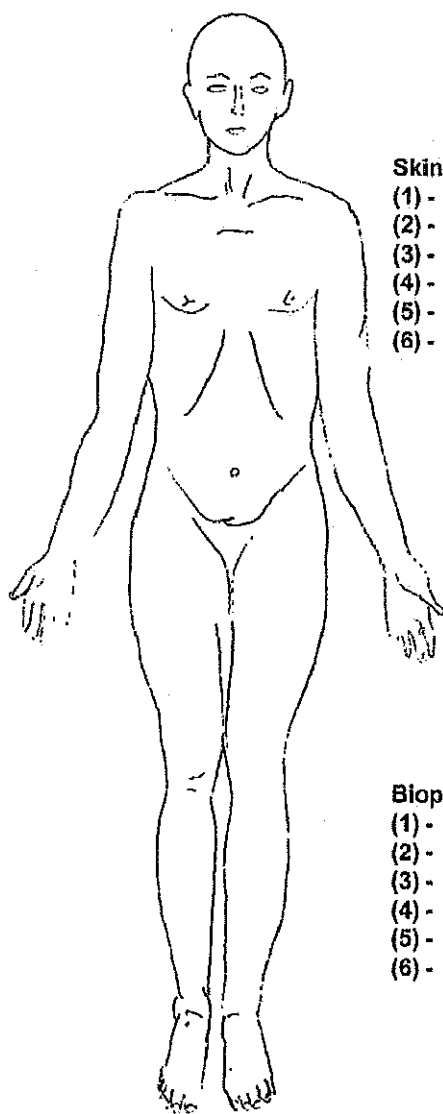
3


2


1


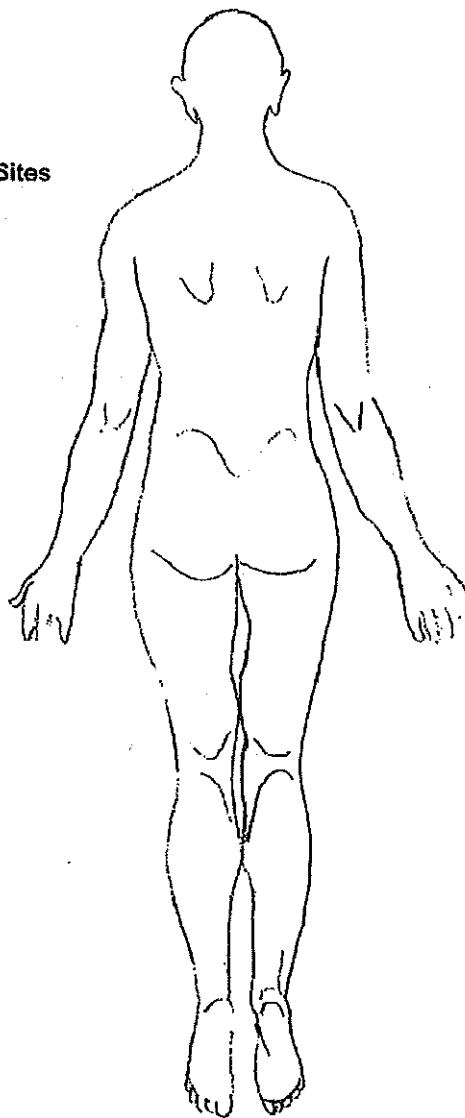
10. Slides should be air-dried and **NEVER** heat fixed.
11. A Band Aid is generally sufficient to protect the smear site.
12. A single technician takes all smears to provide for more uniform and consistent results.
13. The smears may be sent to the National Hansen's Disease Programs for reading.
14. A chart to diagram sites of the skin smears or biopsy is attached to "Skin Biopsy" in the appendix. It can be copied for your convenience.

NATIONAL HANSEN'S DISEASE PROGRAMS		SKIN SMEAR / BIOPSY CHART	DATE: _____
Patient's Name (Last, First, Middle): _____			HD ID No: _____
Date of Birth: _____	Social Security No.: _____	Phone results to: _____	



Skin Smear Sites

- (1) -
- (2) -
- (3) -
- (4) -
- (5) -
- (6) -



Biopsy Sites

- (1) -
- (2) -
- (3) -
- (4) -
- (5) -
- (6) -

Private Physician:

Name: _____

Address: _____

STAINING OF SKIN SMEARS

1. Dry the slide with smear at room temperature. **DO NOT HEAT FIX.**
2. Place slides on a staining rack and flood with 10% formalin for 15 minutes for fixation.
3. Rinse with tap water.
4. Flood slides with Ziehl-Neelsen carbol-fuchsin for twenty minutes. (Always filter stain before each use.)
5. Rinse with tap water.
6. Decolorize with 2% acid alcohol for 1 minute.
7. Rinse slides thoroughly with tap water.
8. Counterstain with alkaline methylene blue for 30 seconds to 1 minute.
9. Rinse with tap water and air dry.

NOTE: Positive and negative control slides must be used each day for quality control purposes.

Z-N Carbol Fuchsin Stain:

Basic fuchsin.....1.0 gm.
Phenol crystals.....5.0 gms.
95% ethanol.....10.0 mls.
Water, to make.....100.0 mls.

Acid alcohol:

Conc. HCl.....2.0 mls.
95% ethanol.....98.0 mls.

Alkaline Methylene Blue:

KOH (10%).....10.0 mls.
Methylene blue..... 0.35 gms.
95% ethanol..... 16.0 mls.
Water to make..... 100.0 mls.

MICROSCOPIC EXAMINATION OF SKIN SMEARS:

The stained smears are examined with a quality microscope using the oil immersion objective (x100) to determine the total number of bacilli. The same individual should read all smears for the purpose of consistency. The smear will have similar numbers of bacilli throughout, however, four separate quadrants of the smear are examined and averaged to establish the Bacterial Index (BI).

REPORTING THE BACTERIAL INDEX (BI):

The results are reported on a 0 to 6 + semi-logarithmic scale using a descriptive phrase or numerical code. This is an indicator of the total bacillary load of the patient. It falls about 1 point per year during effective treatment as dead bacilli undergo lysis and are absorbed.

Very Numerous (+6) -	over 1000 bacilli per oil immersion field.
Numerous (+5) -	100 to 1000 bacilli per oil immersion field.
Moderate (+4) -	10 to 100 bacilli per oil immersion field.
Few (+3) -	1 to 10 bacilli per oil immersion field.
Very few (+2) -	1 to 10 bacilli per 10 fields.
Rare (+1) -	1 to 10 bacilli per 100 fields.
None found (NF) -	No AFB seen on entire site.

STANDARDS FOR PERFORMANCE OF HAND SCREEN

The hand screen is intended to record the baseline and risk assessment of patients requiring acute care, or receiving health education, and it helps identify patients in need of treatment to prevent progressive nerve damage (decrease in sensory and muscle function). The majority of patients may not have sensory or muscle involvement of the hands or will have long-standing involvement that is not changing.

Long standing sensory and muscle loss that is unchanging does not need treatment of the nerve, however, the patient may benefit from deformity prevention techniques (splinting/education/adaptive devices).

The sensory testing device used with the Hand Screen is a set of five (5) calibrated nylon filaments mounted on a small rod, which measures levels of coetaneous touch and pressure on a scale of 2.83 to 6.65. The normal threshold level is 2.83.

WHEN TO PERFORM THE SCREEN

- A baseline hand screen is performed on all new patients at the time of diagnosis.
- Screens are performed on a quarterly basis as patients are scheduled for laboratory monitoring during chemotherapy for HD.
- Screens shall also be performed as clinically necessary on any patient complaining of muscle weakness, decrease in sensation, or change in function.

PATIENTS WITH NERVE CHANGES:

Patients whose sensory and muscle function has deteriorated over the last 6-12 months are experiencing reaction in the nerves; these are considered "acute" nerves.

Patients with "acute" nerves need immediate attention in order to prevent progression in nerve involvement, and examination by the physician for treatment of the nerve with corticosteroids or other anti-inflammatory agents.

Referral to an occupational therapist may be warranted for patient education in reducing stress on the acute nerve, protection of the nerve, or temporary immobilization.

HAND SCREEN INSTRUCTIONS

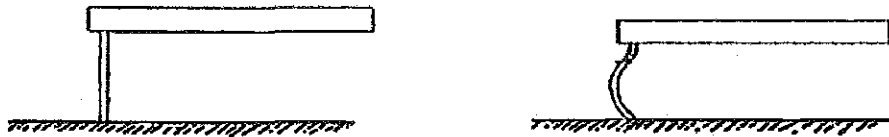
PATIENT DATA:

Use middle initial or middle name if available.

Use patient's social security number.

SECTION I SENSORY TEST:

- A. Perform the test with the patient's eyes closed or averted.
- B. Select the sites to be tested as indicated on the Hand Screen form.
- C. Use Filament #1, the lightest, first. If equates to normal sensation (0.05 gram).
- D. Apply the filament slowly to bending (just before bending to the heaviest), hold 1.5 seconds, remove slowly.



- E. Apply the filament three times (slowly) in succession and record if the patient feels any of the three applications.
- F. If the first filament is not felt, proceed to the next heavier filament, repeating the process until a filament is felt.
- G. Record the number of the filament first felt in the appropriate blank, next to the appropriate number. If no filament is felt, put a zero in the blank to indicate the test was completed for that site, but the patient did not respond.
- H. Do not allow the filament to slide across the skin.
- I. Ask the patient to reply "yes" when the filament is felt.
- J. Apply the filament along the margin of and NOT on an ulcer site, callous or scar.

SECTION II SKIN INSPECTION:

Use initials indicated on form to mark hand map and for lesions and observations made of the condition of the patient's hands.

SECTION III MUSCLE TESTING:

Results of muscle testing are graded as strong, weak, or paralyzed.

Strong – Normal ROM and full resistance

Weak – Reduced ROM with reduced or no resistance

Paralyzed – No contraction palpable.

1. Abduction of index finger (ulnar).
Index finger should be abducted with some slight flexion in the knuckle joint, with all other joints straight. Apply resistance at the base of the index finger. Thumb of supporting hand can palpate for possible muscle contraction.
2. Abduction of little finger (ulnar).
Ask patient to move little finger out and slightly up, palm side up, keeping all the joints of the finger straight. Apply resistance at the base of the little finger. Fingers of your supporting hand will be able to palpate for possible muscle contraction.
3. Abduction of the thumb (median).
Move thumb away from palm of hand at right angles to the plane of the palm of the hand. Resistance is applied at the base of the thumb, pushing it in to the index finger.
4. Opposition of the thumb (median).
Have patient make ring with thumb and little finger, try to push thumb out.
5. Wrist extension (radial).
Ask the patient to make a fist, and try to push the wrist down on the radial side. If weakness is present, patient may not be able to resist or wrist may deviate to unaffected side.

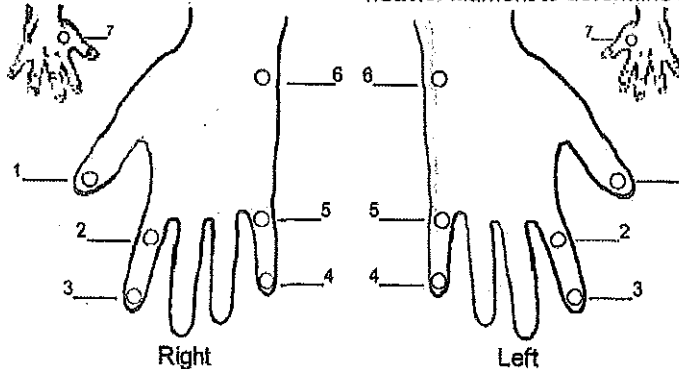
SECTION IV PERIPHERAL NERVE RISK:

Weakness or paralysis is usually not present wherever normal sensation or sweating is found. Loss of sensation and weakness may occur at the same time or sometimes months or years later.

Peripheral nerve involvement of short duration is more apt to be responsive to treatment. Acute nerve involvement may be successfully minimized or reversed by treatment with corticosteroids, anti-inflammatory agents, immobilization,

PROGRAM NAME:		HAND SCREEN RECORD		Date:
Patient's Name (Last, First, Middle):			SS No.	Reaction: Type I ____ Type II ____
Patient's File No.	Medications:	Date of Disease Onset	Classification	Initial ____ F/U ____

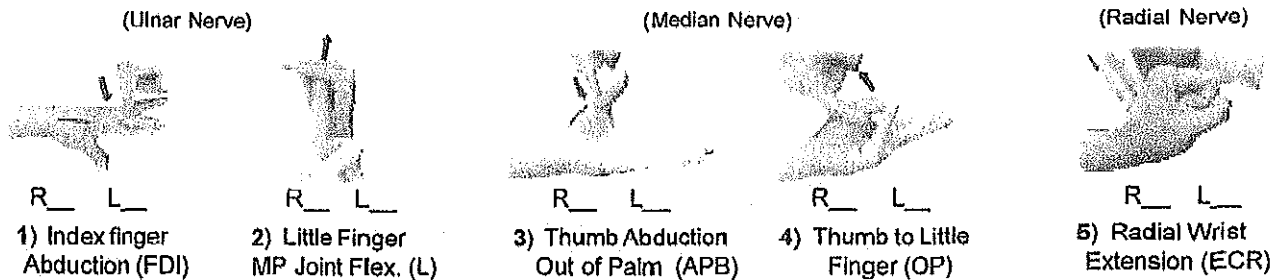
Section I. **SENSORY TESTING:** Use first filament (A) at site indicated (*apply three times*). If no response, use next heavier filament to determine level of loss.



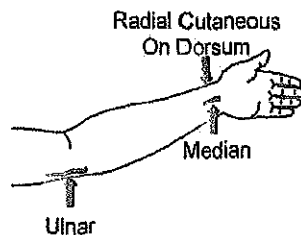
Filament	Force, gms	Interpretation	(Grade Pts.)
A Green (2.83)	0.05	Normal	(5)
B Blue (3.61)	0.20	Residual Texture	(4)
C Purple (4.31)	2.00	Residual Protective Sensation	(3)
D Red (4.56)	4.00	Loss of Protective Sensation	(2)
E Orange (6.65)	300.00	Residual Deep Pressure	(1)

Section II. **SKIN INSPECTION:** Draw and label (*above*): W - Wound, C - Callus, S - Swelling, R - Redness, D - Dryness, T - Temperature, M - Missing, J - Contracture, O - Other

Section III. **MUSCLE TESTING:** Mark (*below*): S = Strong, W = Weak, P = Paralysis (or Grade 5 to 0)



Section IV. **PERIPHERAL NERVE RISK:** Mark: U, M, R (*or combination*)



- | | |
|---|---------------|
| 1) Enlarged or swollen nerve | R ____ L ____ |
| 2) Tender / painful on stretch or compression | R ____ L ____ |
| 3) Sensory change in the last 12 months | R ____ L ____ |
| 4) Muscle change in the last 12 months | R ____ L ____ |

High Risk (*acute or changing nerve*): Yes ____ No ____
(refer to physician/therapist)

Section V. **DEFORMITY RISK:** (*Check if present*)

- | | | | |
|--|---------------|---|---------------|
| 1) Loss of Protective Sensation | R ____ L ____ | 4) Injuries (<i>wounds, blisters, etc.</i>) | R ____ L ____ |
| 2) Clawed but Mobile Hand | R ____ L ____ | 5) Contracted or Stiff Joints | R ____ L ____ |
| 3) Fingertip Absorption (<i>Mild ____ Severe ____</i>) | R ____ L ____ | 6) Wrist Drop (<i>radial nerve</i>) | R ____ L ____ |

High Risk (*any of the above*): Yes ____ No ____
(refer for appropriate treatment)

Has there been a change in the hand since any previous exam? Yes ____ No ____

Examined by: _____

wrapping to keep it warm, or possibly surgery (nerve transfer).

Classification is graded on a scale of 1 to 4.

Risk Category 1:

A patient in this category may need to be followed for the possibility of further problems.

Risk Category 2:

Tender nerve on stretch or compression, with the ulnar nerve in the area of the olecranon process in the elbow. May be tender on flexion of arm or if pressure applied to area. To palpate for an enlarged nerve, use the four fingers of one hand and gently roll the nerve under them. A normal nerve is slightly thick or may not be palpable at all. A hard, sclerosed nerve is abnormal.

Risk Category 3:

Sensory change in the last 12 months.

Risk Category 4:

Muscle change in the last 12 months.

Section V

DEFORMITY RISK:

This is classified from a range of 1 to 5, which lists types of disability which may be present in a patient.

STANDARDS FOR PERFORMANCE OF THE FOOT SCREEN

The initial foot screen is intended to record the baseline status of patient subjective data and clinical signs and symptoms of neurological impairment. The foot screen evaluates history or presence of plantar ulceration, strength of specific muscles, plantar foot sensation, and deformities which can place the foot at risk of injury. After the initial evaluation, screens are performed annually to monitor or pick up any undetected changes by the patient and are indicated more often if the patient perceives any change in sensory, motor or functional status. The screen is a tool to bring up any treatment issues such as wound, callus, and toenail care, footwear and orthotic needs.

The Screen is also used to place the patient in a Risk Category. The foot screen assessment section or risk category serves as a guideline for routine foot checks. This check up is for monitoring and trimming plantar callus and toenails and for checking on appropriateness of patient footwear and orthotics.

The sensory testing device used with the Foot Screen is a nylon filament mounted on a holder and is designed to deliver a 10 gram force when properly applied. Our research has shown that a patient who can feel the 10 gram filament in the selected sites will not develop ulcers.

Rating categories are based on the objective data and are defined as follows:

- Category 0 - No Loss of Protective Sensation (LOPS)
- Category 1 - LOPS but no deformity
- Category 2 - LOPS and deformity
- Category 3 - LOPS and history of ulceration
- Category 4 - Charcot foot

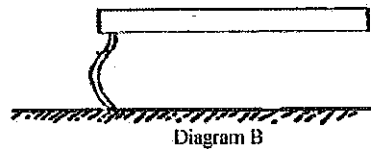
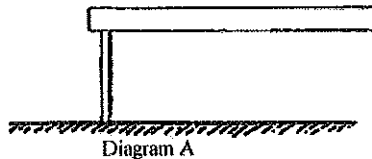
WHEN TO PERFORM THE SCREEN

- A baseline hand screen is performed on all new patients at the time of diagnosis.
- Screens are performed on a quarterly basis as patients are scheduled for laboratory monitoring during chemotherapy for HD.
- Screens shall also be performed as clinically necessary on any patient complaining of muscle weakness, decrease in sensation, or change in function.

FOOT SCREEN ENCOUNTER FORM

Instructions for sensory testing on the foot:

1. Use the 10 gram filament provided to test sensation.
2. Select the sites to be tested based on the Foot Screening Form.
3. Apply the filament perpendicular to the skin's surface. (See diagram A)
4. The approach, skin contact and departure of the filament should be approximately 1 ½ seconds duration.
5. Apply sufficient force to cause the filament to bend (See diagram B)



6. Do not allow the filament to slide across the skin or make repetitive contact at the test site.
7. Randomize the selection of test sites and time between successive tests to reduce the potential for patient guessing.
8. Ask the patient to respond "yes" when the filament is felt.
9. Apply the filament along the perimeter of and NOT on an ulcer site, callous, scar or necrotic tissue.
10. Foot screens are performed annually. If the patient has symptoms of neuritis, e.g., burning on the soles of the feet, pain in the lower extremities, or is on treatment for neuritis, the foot screen should be done more frequently to monitor progress or to refer to the clinician.
11. A copy of the Foot Screen must be sent to the NHDP.

HD CLINIC	FOOT SCREEN RECORD		DATE:
PATIENT'S NAME (Last, First, Middle)		SS#	REACTION: TYPE I _____ TYPE II _____
PATIENT'S FILE NO:	MEDICATIONS:	DATE OF HD ONSET:	CLASSIFICATION:
LOWER EXTREMITY SURGERY:		TYPE OF WORK USUALLY DONE:	

Fill in the following blanks with R, L, or B to indicate positive findings on the right, left or both feet.

Has there been a change in the foot since last evaluation? Yes _____ No _____

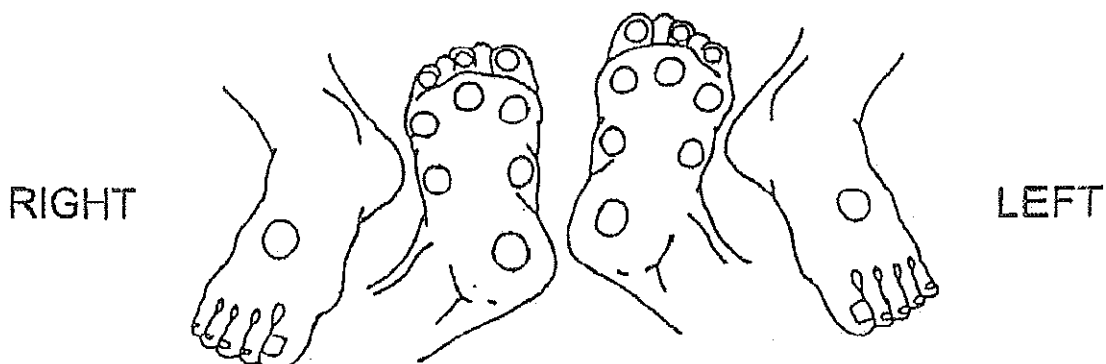
Is there a foot ulcer now or history of foot ulcer? Yes _____ No _____

Does the foot have an abnormal shape? Yes _____ No _____

Is there weakness in the ankle or foot? Yes _____ No _____

Are the nails thick, too long or ingrown? Yes _____ No _____

Label: Sensory level with a "+" in the circled areas of the foot if the patient can feel the 10 gram (5.07 Semmes-Weinstein) nylon filament and "-" if he/she can not feel the 10 gram filament.



Clinical Appearance Of Skin:

Does the patient use footwear appropriate for his/her category? Yes _____ No _____

RISK CATEGORY: _____

_____ 0 No protective sensory loss

_____ 1 Loss of protective sensation (no deformity, or plantar ulcer history).

_____ 2 Loss of protective sensation and deformity (no plantar ulcer history).

_____ 3 History of plantar ulcer.

PATIENT EDUCATION: Skin care, inspection, footwear

REFERRALS: _____

Date of Next Evaluation: Category 0 - One Year _____

Category 1 - One Year _____

Category 2 - Six Months _____








Category 3 - One - Three Months _____

WHO GRADING OF DISABILITIES HANDS AND FEET

- Grade 0: No anesthesia, visible deformity, or damage
- Grade 1: Anesthesia present, but no visible deformity or damage
- Grade 2: Visible deformity or damage present

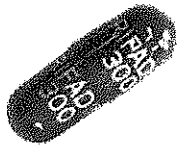






Each hand and foot should be assessed and graded separately. Damage in this context includes ulceration, shortening, disorganization, stiffness, or loss of part or all of the hand or foot. If any disability found in the patient is due to causes other than leprosy, this fact should be noted.

HANSEN'S DISEASE MEDICATIONS

DRUG NAME	DRUG DOSAGE	HOW TO TAKE **	COMMON SIDE EFFECTS
RIFAMPIN 300 mg 	TAKE AS DIRECTED BY PHYSICIAN DIRECTIONS:	TAKE ON AN EMPTY STOMACH 1 HOUR BEFORE MEALS OR 2 HOURS AFTER MEALS	May color urine, sweat, sputum, tears red. May upset stomach or give you flu-like symptoms. Often interferes with other medicine. Inform us if you are taking any new medicines, even birth control pills.
DAPSONE 25 mg  100 mg 	TAKE AS DIRECTED BY PHYSICIAN DIRECTIONS:	CAN TAKE ON EMPTY OR FULL STOMACH	May cause muscles weakness or give you a sore throat and fever. If this happens, stop the drug and call HD clinic nurse.
CLOFAZIMINE 50 mg 	TAKE AS DIRECTED BY PHYSICIAN DIRECTIONS:	TAKE WITH FOOD	May color skin, urine, sweat, sputum or whites of eyes brown. Skin may become dry; use lotion on skin at least twice a day.
PREDNISONE <i>(drug may vary in colors / sizes)</i> 5 mg  20 mg 	TAKE AS DIRECTED BY PHYSICIAN DIRECTIONS:	TAKE WITH FOOD	<u>Drug must be gradually decreased.</u> NEVER ABRUPTLY STOP DRUG! Take as directed by MD. May have increased appetite or increased energy.
MINOCYCLINE 100 mg 	TAKE AS DIRECTED BY PHYSICIAN DIRECTIONS:	MAY BE TAKEN ON AN EMPTY OR FULL STOMACH DO NOT TAKE ANTACIDS OR IRON SUPPLEMENTS WHILE TAKING THIS MEDICINE	Wear sunscreen in sunlight. Dizziness can occur. Stop medicine if hives develop. Women can get yeast infections. Call HD nurse if you develop any symptoms of a yeast infection: Vaginal discharge or vaginal itching/burning.

** NOTE: All medications should be taken with a full glass of water.

MEDICINAS PARA LA ENFERMEDAD DE HANSEN

DROGA	DOSIS	COMO SE TOMA**	EFFECTOS SECUNDARIOS
RIFAMPIN 300 mg 	TOME COMO INDICADO POR SU MEDICO DIRECCIONES:	TOME EN AYUNAS 1 HORA ANTES DE COMER O 2 HORAS DESPUES DE COMER NO TOME ANTIACIDOS (TUMS, ect) Durante una hora de haberse tomado	Puede enrojecer la orina, esputo, o la lágrimas. Puede irritar el estómago o causar síntomas parecidos a los de la gripe. Puede interferir con otras medicinas. Avisenos si es que está tomando cualquier medicina incluyendo pastillas anticonceptivas.
DAPSONE 25 mg  100 mg 	TOME COMO INDICADO POR SU MEDICO DIRECCIONES:	TOME EN AYUNAS O DESPUES DE COMER	Puede provocar debilidad muscular, dolor de garganta y fiebre. En dado caso, descontinúe la droga y llame a la enfermera de la clínica HD
CLOFAZIMINE 50 mg 	TOME COMO INDICADO POR SU MEDICO DIRECCIONES:	TOME CON COMIDA	Puede alterar el color de la piel, orina, sudor, y esputo, o la parte blanca de los ojos. Puede resecarle la piel. Use una loción para la piel por lo menos dos veces al día.
PREDNISONE <i>(puede variar de color/tamaño)</i> 5 mg  20 mg 	TOME COMO INDICADO POR SU MEDICO DIRECCIONES:	TOME CON COMIDA	<u>Se debe disminuir gradualmente la dosis de esta droga. NO SE DEBE DETENER BRUSCAMENTE!</u> Tome como le indique su DOCTOR. Puede aumentar su apetito o energía.
MINOCYCLINE 100 mg 	TOME COMO INDICADO POR SU MEDICO DIRECCIONES:	SE PUEDE TOMAR EN AYUNAS O DESPUES DE COMER NO TOME ANTIACIDOS NI SUPLEMENTOS DE HIERRO DURANTE DOS HORAS ANTES O DESPUES DE TOMAR ESTA MEDICINA	Aplicase bloqueador de sol. Puede causar mareos. Detenga la medicina si le salen ronchas. Las mujeres pueden sufrir infecciones de ciertos hongos. Llame a la enfermera de la clínica HD si sufre cualquier síntoma de infección: flujo vaginal, comezon/ardor.

** NOTE Tome toda medicina con un vaso de agua

Instructions for Completing the Hansen's Disease (Leprosy) Surveillance Form

The Hansen's Disease or Leprosy Surveillance Form (LSF) is the document used to report leprosy cases to the U.S. National Hansen's Disease Registry. These data are used for epidemiological, clinical, and basic research studies throughout the National Hansen's Disease Program (NHDP), and are the official source for information on leprosy cases in the U.S.

The information requested on the LSF is used by many clinicians and researchers, and collection of all information is highly desirable. However, the fields that are **boldfaced** on the form and in the instructions below are considered to be the minimal information needed to register a patient. Failure to provide this information will result in the form being returned which creates additional work and may cause delays in obtaining program services for the patient.

1. **Reporting State:** Use the abbreviation of the state from which the report is being sent. This is usually the state of the clinician's office and not necessarily the patient's resident state.
2. **Date of Report:** This is date of the initial LSF completion. If patient was previously reported and has relapsed, write the word "RELAPSE" next to the date.
3. **Social Security Number:** self-explanatory.
4. **Patient Name:** Self-explanatory.
5. **Present Address:** Please include the county and zip code which are used to geographically cluster patients.
6. **Place of Birth:** Include state and county, if born in the U.S., or the country, if foreign born.
7. **Date of Birth/Sex:** Self-explanatory.
8. **Race/Ethnicity:** This information should be voluntarily provided by the patient. If the patient refuses or indicates a race/ethnicity category not listed, check the "Not Specified" box.
9. **Date Entered the U.S.:** For patients who have immigrated to the U.S., provide the month and year of entry.
10. **Date of Onset of Symptoms:** This information is usually the patient's recollection of when classic leprosy symptoms (*rash, nodule formation, paresthesia, decreased peripheral sensation, etc.*) were first noticed.
11. **Date Leprosy First Diagnosed:** Provide the month and year a diagnosis was made. This usually coincides with a biopsy date if one was performed.
12. **Initial Diagnosis:** Was the patient diagnosed in the U.S. or outside the U.S.
13. **Type of Leprosy:** Classify the diagnosis based on one of the ICD-9-CM diagnosis codes. (NHDP Clinic physicians: Please circle specific classification, if possible)
 - 030.0 Lepromatous Leprosy (*macular, diffuse, infiltrated, nodular, neuritic – includes Ridley-Jopling [RJ], Lepromatous [LL] and Borderline lepromatous [BL]*):** A form marked by erythematous macules, generalized papular and nodular lesions, and variously by upper respiratory infiltration, nodules on conjunctiva or sclera, and motor loss.
 - 030.1 Tuberculoid Leprosy (*macular, maculoanesthetic, major, minor, neuritic – includes RJTuberculoid [TT] and Borderline tuberculoid [BT]*):** A form marked by usually one lesion with well-defined margins with scaly surface and local tender cutaneous or peripheral nerves.
 - 030.2 Indeterminate (*uncharacteristic, macular, neuritic*):** A form marked by one or more macular lesions, which may have slight erythema.
 - 030.3 Borderline (*dimorphous, infiltrated, neuritic – includes RJ Borderline [BB] or true mid disease only*):** A form marked by early nerve involvement and lesions of varying stages.
 - 030.8 Other Specified Leprosy:** Use this code when the diagnosis is specified as a "leprosy" but is not listed above (030.0-030.3).
 - 030.9 Leprosy, Inactive:** Use this code when the diagnosis is identified as a "leprosy" but inactive.
14. **Diagnosis of Disease:** Enter INITIAL biopsy and skin smear dates and results.
15. **Residence (*Pre-diagnosis*):** List all cities, counties, and states in the U.S. and all foreign countries a patient resided in BEFORE leprosy was diagnosed. This information is used to map all places where U.S. leprosy cases have resided.
16. **Disability:** Indicate any sensory abnormalities or deformities of the hands and feet or lagophthalmos of the eyes.
17. **Current Household Contacts:** Self-explanatory.
18. **Current Treatment for Leprosy:** Date treatment started and indicate all drugs used for initial treatment.
19. **Name and Address of Physician or Investigator:** Self-explanatory.

HANSEN'S DISEASE (LEPROSY) SURVEILLANCE FORM

NATIONAL HANSEN'S DISEASE PROGRAMS

1770 PHYSICIANS PARK DRIVE

BATON ROUGE, LA 70816

1-800-642-2477

1 Reporting State <div style="border: 1px solid black; width: 40px; height: 20px; margin: 5px auto;"></div>	2 Date of Report <div style="display: flex; justify-content: space-around; font-size: small;"> Mo.DayYr. </div> <div style="display: flex; justify-content: space-around; margin-top: 5px;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div>	3 Social Security Number (optional) <div style="border-bottom: 1px solid black; width: 100%; margin-top: 5px;"></div>																																																																				
4 Patient Name: (Last) _____ (First) _____ (Middle) _____																																																																						
5 Present Address: <div style="display: flex; justify-content: space-between;"> <div>Street _____</div> <div>City _____</div> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div>County _____</div> <div>State _____ Zip _____</div> </div>																																																																						
6 Place of Birth: <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div>State _____</div> <div>County _____</div> </div> <div style="margin-top: 5px;">Country _____</div>	7 Date of Birth: <div style="display: flex; justify-content: space-around; font-size: small;"> Mo.DayYr. </div> <div style="display: flex; justify-content: space-around; margin-top: 5px;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female																																																																					
8 Race/Ethnicity: <div style="display: flex; flex-wrap: wrap; font-size: small;"> <div style="width: 50%;"><input type="checkbox"/> White, Not Hispanic</div> <div style="width: 50%;"><input type="checkbox"/> White, Hispanic</div> <div style="width: 50%;"><input type="checkbox"/> American Indian, Alaska Native</div> <div style="width: 50%;"><input type="checkbox"/> Indian, Middle Easterner</div> <div style="width: 50%;"><input type="checkbox"/> Black, Not Hispanic</div> <div style="width: 50%;"><input type="checkbox"/> Black, Hispanic</div> <div style="width: 50%;"><input type="checkbox"/> Asian, Pacific Islander</div> <div style="width: 50%;"><input type="checkbox"/> Not Specified</div> </div>																																																																						
9 Date Entered U.S.: <div style="display: flex; justify-content: space-around; font-size: small;"> Mo.Yr. </div> <div style="display: flex; justify-content: space-around; margin-top: 5px;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div>	10 Date of Onset of Symptoms: <div style="display: flex; justify-content: space-around; font-size: small;"> Mo.Yr. </div> <div style="display: flex; justify-content: space-around; margin-top: 5px;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div>	11 Date Leprosy First Diagnosed: <div style="display: flex; justify-content: space-around; font-size: small;"> Mo.Yr. </div> <div style="display: flex; justify-content: space-around; margin-top: 5px;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div>																																																																				
12 Initial Diagnosis in: <input type="checkbox"/> U.S. <input type="checkbox"/> Outside U.S.																																																																						
13 Type of Leprosy: (ICD-9-CM Code) (NHDP Clinic physicians: Please circle specific classification, if possible) <div style="display: flex; justify-content: space-between; font-size: small;"> <div><input type="checkbox"/> Lepromatous (030.0 - LL, BL)</div> <div><input type="checkbox"/> Indeterminate (030.2 - IN)</div> <div><input type="checkbox"/> Other Specified Leprosy (030.8)</div> </div> <div style="display: flex; justify-content: space-between; font-size: small;"> <div><input type="checkbox"/> Tuberculoid (030.1 - TT, BT)</div> <div><input type="checkbox"/> Borderline (030.3 - BB)</div> <div><input type="checkbox"/> Leprosy, Unspecified (030.9)</div> </div>																																																																						
14 Diagnosis of Disease: Was biopsy performed in U.S. <input type="checkbox"/> Yes <input type="checkbox"/> No Date ____ / ____ / ____ Result _____ Skin Smear <input type="checkbox"/> Yes <input type="checkbox"/> No Date ____ / ____ / ____ Bt: Positive ____ Negative ____	15 List all places in the U.S.A. and all foreign countries a PATIENT resided (including Military Service) BEFORE leprosy was diagnosed. <table border="1" style="width:100%; border-collapse: collapse; font-size: x-small;"> <thead> <tr> <th rowspan="2">TOWN</th> <th rowspan="2">COUNTY</th> <th rowspan="2">STATE</th> <th rowspan="2">COUNTRY</th> <th colspan="2">INCLUSIVE DATES</th> </tr> <tr> <th>From Mo/Yr.</th> <th>To Mo/Yr.</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>		TOWN	COUNTY	STATE	COUNTRY	INCLUSIVE DATES		From Mo/Yr.	To Mo/Yr.																																																												
TOWN	COUNTY	STATE					COUNTRY	INCLUSIVE DATES																																																														
			From Mo/Yr.	To Mo/Yr.																																																																		
16 Disability: <table style="width:100%; font-size: x-small;"> <tr> <th></th> <th>Hands</th> <th>Feet</th> <th>Eyes</th> </tr> <tr> <td></td> <td>Yes / No</td> <td>Yes / No</td> <td></td> </tr> <tr> <td>Sensory Loss</td> <td><input type="checkbox"/> <input type="checkbox"/></td> <td><input type="checkbox"/> <input type="checkbox"/></td> <td>Lagophthalmos?</td> </tr> <tr> <td>Deformity</td> <td><input type="checkbox"/> <input type="checkbox"/></td> <td><input type="checkbox"/> <input type="checkbox"/></td> <td>Yes <input type="checkbox"/> No <input type="checkbox"/></td> </tr> </table>		Hands	Feet	Eyes		Yes / No	Yes / No		Sensory Loss	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	Lagophthalmos?	Deformity	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	17 Current Household Contacts: <table style="width:100%; font-size: x-small;"> <tr> <th style="width: 80%;">Name/Relationship</th> </tr> <tr><td>1 _____</td></tr> <tr><td>2 _____</td></tr> <tr><td>3 _____</td></tr> <tr><td>4 _____</td></tr> <tr><td>5 _____</td></tr> </table>		Name/Relationship	1 _____	2 _____	3 _____	4 _____	5 _____																																														
	Hands	Feet	Eyes																																																																			
	Yes / No	Yes / No																																																																				
Sensory Loss	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	Lagophthalmos?																																																																			
Deformity	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>																																																																			
Name/Relationship																																																																						
1 _____																																																																						
2 _____																																																																						
3 _____																																																																						
4 _____																																																																						
5 _____																																																																						
18 Current Treatment for Leprosy: (check all that apply) Date Treatment Started: ____ / ____ / ____ <div style="display: flex; justify-content: space-between; font-size: small;"> <div> <input type="checkbox"/> Dapsone <input type="checkbox"/> Rifampin <input type="checkbox"/> Clofazimine <input type="checkbox"/> Other (list) _____ </div> <div> <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ </div> </div>																																																																						
19 Name and Address of Physician: _____ Investigator: _____																																																																						

This form may be FAXED to NHDP at (225) 756-3706

A copy of this form should be sent to your local or state health department.

NHDP
Rev. 8/2012

HD CLINIC	CHANGE OF INFORMATION	DATE
Last Name, First name, Middle Initial		
Date of Birth:	Social Security No.	

☐ Check box if there are any changes in the above information.

In accordance with the national Hansen's Disease Program Policy, the following change is reported:

The above patient has:

☐ Relocated To:

 City State Zip

 Hansen's Disease Clinic

☐ Left the Country

☐ Deceased: _____
 Date

HANSEN'S DISEASE CLINICS***National Hansen's Disease Programs
Ambulatory Care Program*****Webpage:** www.hrsa.gov/hansensdisease**Toll Free Phone Number:** 800-642-2477**ATLANTA HD CLINIC**

Emory MidTown Hospital

550 Peachtree Street NE

7th Floor MOT

Atlanta, GA 30308

PH: (404) 686-5885

Fax: (404) 686-4508

Primary Physicians – Dr. Jessica Fairley/Dr. Phyllis Kozarsky

email: jessica.fairley@emory.eduemail: pkozars@emory.edu

PH: (404) 686-5885

Public Health Nurse: Roberta Dismukes, RN

email: roberta.dismukes@emoryhealthcare.org

PH: (404) 320-6662

PH: (404) 686-7668

BOSTON HD CLINIC

Lahey Medical Center

41 Mall Road

Burlington, MA 01805

PH: (781) 744-5670

Fax: (781) 744-5687

Primary Physician - Dr. Samuel Moschella

email: samuel.l.moschella@lahey.org

Public Health Nurse - Ms. Stephanie Burns, RN, D.N.C.

email: stephanie.a.burns@lahey.org**CHICAGO HD CLINIC**

University of Illinois

College of Medicine at Chicago

Department of Dermatology, (MC 624)

808 S. Wood, RM 376 CME

Chicago, IL 60612

PH: (312) 996-0734

Fax: (312) 355-0870

Primary Physician - Dr. Carlotta Hill

email: chhill@uic.edu

Public Health Nurse – Gladys Lee, RN

email: FLLee@uic.edu**LOS ANGELES HD CLINIC**

LAC+USC Medical Center

1200 N. State St.

Clinic Tower A5B123

Los Angeles, CA 90033

PH: (323) 409-5240

Fax: (323) 441-8152

Primary Physician - Dr. Maria T. Ochoa

email: mariatoc@usc.edu

PH: (323) 226-3373

Public Health Nurse - Helen Mora, RN

email: hmora@dhs.lacounty.gov

Occupational Therapist - Rob Jerskey

email: robjerskey@yahoo.com**MARTINEZ HD CLINIC**

Contra Costa Regional Medical Center

Outpatient Specialty Clinic

2500 Alhambra Avenue

Martinez, CA 94553

PH: (925) 370-5868

Fax: (925) 370-5529

Primary Physician - Drs. Sutherland/Saffier

email: ssutherland@hsd.co.contra-costa.ca.us

PH: (925) 370-5867

email: ksaffier@yahoo.com

PH: (925) 370-5200 Ext.:4743

Public Health Nurse – Barbara Hobson, RN

PH: (925) 313-6757

email: Barbara.Hobson@hsd.cccounty.us

Community Health Worker – Sebastian Basalic

email: Sebastian.Basalic@hsd.cccounty.us**MIAMI HD CLINIC**

Jackson Memorial Hospital

1611 N.W. 12th AvenueACC East – 2nd Floor

Department of Dermatology

Miami, FL 33136-1096

PH: (305) 585-7348

Fax: (305) 585-6397

Primary Physician - Dr. Anne Burdick

email: Aburdick@med.miami.edu

Public Health Nurse - Gail Chepenik, RN

email: gchepenik@jhs.miami.org**NEW YORK HD CLINIC**

Bellevue Hospital Center

Department of Dermatology

462 First Avenue, Room 17-N-7

New York, NY 10016

PH: (212) 562-5670

Fax: (212) 263-6423

Primary Physician - Dr. William Levis

email: william_levis@yahoo.com

Public Health Nurse - Lydia Macwan, RN

PH: (212) 562-6096

email: Lydia.Macwan@bellevue.nychhc.org

Physical Therapist - Louis Iannuzzi, P.T., C.Ped.

email: Lni1@nyu.edu**PHOENIX HD CLINIC**

Maricopa County Health Department

1645 East Roosevelt Street

Phoenix, Arizona 85006

PH: (602) 372-2039

Fax: (602) 372-3862

Primary Physician - Dr. Ronald Pust

Tucson Office: (520) 626-5650

Cell: (520) 668-6441

email: rpust@email.arizona.edu

Public Health Nurse - Eileen Smith, RN

PH: (602) 372-2039

email: eileensmith@mail.maricopa.gov

Physical Therapist - Tracy Carroll, MPH

email: tc Carroll@email.arizona.edu

SAN DIEGO HD CLINIC

HHSA, North Central Regional Center
5055 Ruffin Road, Mail Stop: N-513
San Diego, CA 92123
PH: (858) 573-7338
Fax: (858) 573-7325

Primary Physician - Dr. Erik O. Gilbertson
email: erik.gilbertson@sdcounty.ca.gov
Public Health Nurse - Gina Sandoval, RN, PHN
email: regina.sandoval@sdcounty.ca.gov

SAN JUAN HD CLINIC

University of Puerto Rico
Medical Sciences Campus
School of Medicine - Dept. of Dermatology
P. O. Box 365067
San Juan, PR 00936-5067
PH: (787) 765-7950
Fax: (787) 767-0467

Primary Physician - Dr. Pablo Almodo'var
email: dermatol.rcm@upr.edu
Public Health Nurse - Sonia Santos-Expo'sito, RN, BSN
PH: (787) 758-2525, Ext. 5503
email: sonia.santos@upr.edu

SEATTLE HD CLINIC

Harborview Medical Center
2 West Clinic - 359930, 325 Ninth Avenue
Seattle, WA 98104
PH: (206) 520-5000
Toll Free #: 1-877-520-5000
Fax: (206) 744-5109

Primary Physician - Dr. James Harnisch
email: jpharnisch@comcast.net
Public Health Nurse - Angela Bartels, RN
email: bartelsa@uw.edu

SPRINGDALE HD CLINIC

Joseph H. Bates Outreach Clinic of Washington County
614 E. Emma Avenue, Suite 247
Springdale, AR 72764
PH: (479)-751-3630
Fax: (479)-751-4838

Primary Physician: Linda McGhee, MD
PH: (479) 521-0263
PH: (479) 973-8450 (office)
email: lmcghee@uams.edu
Public Health Nurse - Sandy Hainline Williams, RN
PH: (479) 751-3630
Cell: (479) 422-0190
email: sandra.hainline@arkansas.gov

TEXAS HD CLINICS

Department of State Health Services
Hansen's Disease Program
P. O. Box 149347, Mail Code 1939
Austin, TX 78714-9347
PH: (800) 252-8239
Fax: (512) 365-7824-primary fax
Fax: (512) 533-3167-secondary fax
Nurse Consultant: Linda Brown, MS, RN
PH: (512) 533-3144
email: lindaj.brown@dshs.state.tx.us
Officer Administrator: Kirbi Woods
PH: (512) 739-1876
email: kirbi.woods@dshs.state.tx.us

Dallas County Health & Human Services

2377 N. Stemmons Freeway, Suite 522
Dallas, TX 75207-2710
PH: (214) 819-2010
Fax: (214) 819-6095

Physicians - Dr. Jack Cohen/Dr. Sharon Nations
email: jbcohendo@aol.com
PH: (817) 753-6633 (private practice)
email: sharon.nations@utsouthwestern.edu
PH: (214) 645-8800

Public Health Nurse - Nancy Bernstein, RN, BSN
email: nbernstein@dallascounty.org

Houston Hansen's Disease Clinic

Northside Health Center
8504 Schuller Street
Houston, TX 77093
PH: (832) 393-4804
Fax: (832) 393-5247

Physician - Dr. Terry Williams/Dr. Steven Mays
email: Tmwill3502@aol.com
PH: (281) 332-8571
email: Steven.Mays@uth.tmc.edu
PH: (713) 500-8329

Public Health Nurse - Marion Matsu, RN, CCM
email: Marion.Matsu@houston.tx.gov
Main: (832) 393-4798
Cell: (832) 248-7150

Texas Center for Infectious Disease

2303 S. E. Military Drive
San Antonio, TX 78223
PH: (210) 531-4526
Fax: (210) 531-4508

Physician - Dr. Adriana Vasquez
PH: (210) 531-4565
email: adriana.vasquez@dshs.state.tx.us

Physician - Dr. Lynn Horvath
PH: (210) 531-4524
email: lynn.horvath@dshs.state.tx.us
Public Health Nurse - Debbie Mata, RN
PH: (210) 531-4576
PH: (210) 531-4295
Cell: (210) 389-3568
Appointment Secretary: (210) 531-4526
email: debbie.mata@dshs.state.tx.us

Department of State Health Services Region (HSR) 11

601 W. Sesame Drive
Harlingen, TX 78550
PH: (956) 423-0130
Fax: (956) 444-3295

Physician - Dr. Richard Wing
email: richard.wing@dshs.state.tx.us
Public Health Nurse - Grace Flores, RN
PH: (956) 423-0130, Ext. 5573
email: grace.flores@dshs.state.tx.us

Other Clinics

HAWAII HD CLINIC

Hawaii State Department of Health
Hansen's Disease Community Program
3650 Maunalei Avenue

Honolulu, HI 96816

PH: (808) 733-9831

Fax: (808) 733-9836

Program Manager: Lori Ching, RN

Direct Line/Voice Mail: (808) 733-4663

email: lori.ching@doh.hawaii.gov

Office Physical Address:

Diamond Head Health Center

3627 Kilauea Avenue Room 102

Honolulu, HI 96816

Wage Determination - LA County 2005-2047.txt
 WD 05-2047 (Rev.-11) was first posted on www.wdol.gov on 06/22/2010

REGISTER OF WAGE DETERMINATIONS UNDER
 THE SERVICE CONTRACT ACT
 By direction of the Secretary of Labor

U.S. DEPARTMENT OF LABOR
 EMPLOYMENT STANDARDS ADMINISTRATION
 WAGE AND HOUR DIVISION
 WASHINGTON D.C. 20210

Shirley F. Ebbesen Division of
 Director Wage Determinations

Wage Determination No.: 2005-2047
 Revision No.: 11
 Date Of Revision: 06/15/2010

State: California

Area: California Counties of Los Angeles, Orange
 OCCUPATION NOTES:

Heating, Air Conditioning and Refrigeration: Wage rates and fringe benefits
 can be found on Wage Determinations 1986-0879.

Laundry: Wage rates and fringe benefits can be found on Wage Determination
 1977-1297.

Fringe Benefits Required Follow the Occupational Listing		
OCCUPATION CODE - TITLE	FOOTNOTE	RATE
01000 - Administrative Support And Clerical Occupations		
01011 - Accounting Clerk I		15.83
01012 - Accounting Clerk II		17.77
01013 - Accounting Clerk III		20.27
01020 - Administrative Assistant		28.08
01040 - Court Reporter		19.93
01051 - Data Entry Operator I		12.26
01052 - Data Entry Operator II		13.37
01060 - Dispatcher, Motor Vehicle		22.41
01070 - Document Preparation Clerk		13.75
01090 - Duplicating Machine Operator		13.75
01111 - General Clerk I		11.76
01112 - General Clerk II		14.92
01113 - General Clerk III		17.43
01120 - Housing Referral Assistant		21.90
01141 - Messenger Courier		11.45
01191 - Order Clerk I		16.98
01192 - Order Clerk II		18.53
01261 - Personnel Assistant (Employment) I		18.07
01262 - Personnel Assistant (Employment) II		20.20
01263 - Personnel Assistant (Employment) III		22.53
01270 - Production Control Clerk		23.51
01280 - Receptionist		14.51
01290 - Rental Clerk		16.83
01300 - Scheduler, Maintenance		17.39
01311 - Secretary I		17.39
01312 - Secretary II		19.45
01313 - Secretary III		21.90
01320 - Service Order Dispatcher		19.54
01410 - Supply Technician		26.82
01420 - Survey Worker		19.93
01531 - Travel Clerk I		14.72
01532 - Travel Clerk II		16.02
01533 - Travel Clerk III		17.21
01611 - Word Processor I		15.18
01612 - Word Processor II		16.87

Wage Determination - LA County 2005-2047.txt

01613 - Word Processor III	18.76
05000 - Automotive Service Occupations	
05005 - Automobile Body Repairer, Fiberglass	23.56
05010 - Automotive Electrician	22.18
05040 - Automotive Glass Installer	20.84
05070 - Automotive Worker	20.84
05110 - Mobile Equipment Servicer	19.16
05130 - Motor Equipment Metal Mechanic	23.56
05160 - Motor Equipment Metal Worker	20.84
05190 - Motor Vehicle Mechanic	23.56
05220 - Motor Vehicle Mechanic Helper	18.38
05250 - Motor Vehicle Upholstery Worker	20.40
05280 - Motor Vehicle Wrecker	20.84
05310 - Painter, Automotive	22.18
05340 - Radiator Repair Specialist	20.84
05370 - Tire Repairer	15.47
05400 - Transmission Repair Specialist	23.56
07000 - Food Preparation And Service Occupations	
07010 - Baker	12.28
07041 - Cook I	12.91
07042 - Cook II	14.31
07070 - Dishwasher	10.29
07130 - Food Service Worker	11.20
07210 - Meat Cutter	15.92
07260 - Waiter/Waitress	9.85
09000 - Furniture Maintenance And Repair Occupations	
09010 - Electrostatic Spray Painter	20.45
09040 - Furniture Handler	13.66
09080 - Furniture Refinisher	20.45
09090 - Furniture Refinisher Helper	16.30
09110 - Furniture Repairer, Minor	18.74
09130 - Upholsterer	20.45
11000 - General Services And Support Occupations	
11030 - Cleaner, Vehicles	11.76
11060 - Elevator Operator	11.76
11090 - Gardener	19.21
11122 - Housekeeping Aide	12.58
11150 - Janitor	14.04
11210 - Laborer, Grounds Maintenance	14.40
11240 - Maid or Houseman	10.16
11260 - Pruner	13.27
11270 - Tractor Operator	17.13
11330 - Trail Maintenance Worker	14.40
11360 - Window Cleaner	15.77
12000 - Health Occupations	
12010 - Ambulance Driver	17.82
12011 - Breath Alcohol Technician	17.82
12012 - Certified Occupational Therapist Assistant	26.38
12015 - Certified Physical Therapist Assistant	26.70
12020 - Dental Assistant	17.27
12025 - Dental Hygienist	38.39
12030 - EKG Technician	28.14
12035 - Electroneurodiagnostic Technologist	28.14
12040 - Emergency Medical Technician	17.82
12071 - Licensed Practical Nurse I	18.43
12072 - Licensed Practical Nurse II	20.68
12073 - Licensed Practical Nurse III	23.72
12100 - Medical Assistant	14.82
12130 - Medical Laboratory Technician	19.73
12160 - Medical Record Clerk	16.07
12190 - Medical Record Technician	18.53
12195 - Medical Transcriptionist	19.35
12210 - Nuclear Medicine Technologist	36.54

Wage Determination - LA County 2005-2047.txt

12221 - Nursing Assistant I	10.19
12222 - Nursing Assistant II	11.46
12223 - Nursing Assistant III	12.50
12224 - Nursing Assistant IV	14.03
12235 - Optical Dispenser	17.00
12236 - Optical Technician	15.71
12250 - Pharmacy Technician	17.83
12280 - Phlebotomist	14.03
12305 - Radiologic Technologist	25.24
12311 - Registered Nurse I	31.47
12312 - Registered Nurse II	38.49
12313 - Registered Nurse II, Specialist	38.49
12314 - Registered Nurse III	48.20
12315 - Registered Nurse III, Anesthetist	48.20
12316 - Registered Nurse IV	57.77
12317 - Scheduler (Drug and Alcohol Testing)	25.09
13000 - Information And Arts Occupations	
13011 - Exhibits Specialist I	24.83
13012 - Exhibits Specialist II	30.76
13013 - Exhibits Specialist III	37.63
13041 - Illustrator I	27.84
13042 - Illustrator II	34.51
13043 - Illustrator III	42.16
13047 - Librarian	31.80
13050 - Library Aide/Clerk	16.49
13054 - Library Information Technology Systems Administrator	28.71
13058 - Library Technician	22.40
13061 - Media Specialist I	20.36
13062 - Media Specialist II	22.76
13063 - Media Specialist III	25.38
13071 - Photographer I	17.95
13072 - Photographer II	20.08
13073 - Photographer III	26.61
13074 - Photographer IV	33.56
13075 - Photographer V	40.61
13110 - Video Teleconference Technician	20.08
14000 - Information Technology Occupations	
14041 - Computer Operator I	17.82
14042 - Computer Operator II	19.93
14043 - Computer Operator III	22.89
14044 - Computer Operator IV	25.73
14045 - Computer Operator V	27.35
14071 - Computer Programmer I	(see 1)
14072 - Computer Programmer II	(see 1)
14073 - Computer Programmer III	(see 1)
14074 - Computer Programmer IV	(see 1)
14101 - Computer Systems Analyst I	(see 1)
14102 - Computer Systems Analyst II	(see 1)
14103 - Computer Systems Analyst III	(see 1)
14150 - Peripheral Equipment Operator	17.82
14160 - Personal Computer Support Technician	25.73
15000 - Instructional Occupations	
15010 - Aircrew Training Devices Instructor (Non-Rated)	34.73
15020 - Aircrew Training Devices Instructor (Rated)	42.03
15030 - Air Crew Training Devices Instructor (Pilot)	50.37
15050 - Computer Based Training Specialist / Instructor	34.73
15060 - Educational Technologist	36.09
15070 - Flight Instructor (Pilot)	50.37
15080 - Graphic Artist	26.72
15090 - Technical Instructor	25.70
15095 - Technical Instructor/Course Developer	31.47
15110 - Test Proctor	20.77

Wage Determination - LA County 2005-2047.txt

15120 - Tutor	20.77
19000 - Machine Tool Operation And Repair Occupations	
19010 - Machine-Tool Operator (Tool Room)	18.52
19040 - Tool And Die Maker	23.95
21000 - Materials Handling And Packing Occupations	
21020 - Forklift Operator	14.54
21030 - Material Coordinator	23.51
21040 - Material Expediter	23.51
21050 - Material Handling Laborer	13.02
21071 - Order Filler	13.31
21080 - Production Line Worker (Food Processing)	14.54
21110 - Shipping Packer	15.08
21130 - Shipping/Receiving Clerk	15.08
21140 - Store Worker I	11.53
21150 - Stock Clerk	17.13
21210 - Tools And Parts Attendant	14.54
21410 - Warehouse Specialist	14.54
23000 - Mechanics And Maintenance And Repair Occupations	
23010 - Aerospace Structural Welder	30.78
23021 - Aircraft Mechanic I	29.10
23022 - Aircraft Mechanic II	30.78
23023 - Aircraft Mechanic III	31.94
23040 - Aircraft Mechanic Helper	20.38
23050 - Aircraft, Painter	24.41
23060 - Aircraft Servicer	23.55
23080 - Aircraft Worker	24.58
23110 - Appliance Mechanic	20.11
23120 - Bicycle Repairer	15.47
23125 - Cable Splicer	32.84
23130 - Carpenter, Maintenance	27.67
23140 - Carpet Layer	21.12
23160 - Electrician, Maintenance	30.18
23181 - Electronics Technician Maintenance I	23.67
23182 - Electronics Technician Maintenance II	25.21
23183 - Electronics Technician Maintenance III	26.76
23260 - Fabric Worker	23.87
23290 - Fire Alarm System Mechanic	22.33
23310 - Fire Extinguisher Repairer	20.03
23311 - Fuel Distribution System Mechanic	25.94
23312 - Fuel Distribution System Operator	19.83
23370 - General Maintenance Worker	23.26
23380 - Ground Support Equipment Mechanic	29.10
23381 - Ground Support Equipment Servicer	23.55
23382 - Ground Support Equipment Worker	24.58
23391 - Gunsmith I	20.03
23392 - Gunsmith II	23.16
23393 - Gunsmith III	26.19
23430 - Heavy Equipment Mechanic	28.30
23440 - Heavy Equipment Operator	32.18
23460 - Instrument Mechanic	27.13
23465 - Laboratory/Shelter Mechanic	24.67
23470 - Laborer	12.49
23510 - Locksmith	20.69
23530 - Machinery Maintenance Mechanic	27.12
23550 - Machinist, Maintenance	25.41
23580 - Maintenance Trades Helper	14.82
23591 - Metrology Technician I	27.13
23592 - Metrology Technician II	28.74
23593 - Metrology Technician III	31.63
23640 - Millwright	25.45
23710 - Office Appliance Repairer	20.86
23760 - Painter, Maintenance	21.05
23790 - Pipefitter, Maintenance	25.74

Wage Determination - LA County 2005-2047.txt

23810 - Plumber, Maintenance	24.24
23820 - Pneudraulic Systems Mechanic	26.19
23850 - Rigger	26.81
23870 - Scale Mechanic	23.16
23890 - Sheet-Metal Worker, Maintenance	24.34
23910 - Small Engine Mechanic	18.70
23931 - Telecommunications Mechanic I	26.30
23932 - Telecommunications Mechanic II	27.86
23950 - Telephone Lineman	24.18
23960 - Welder, Combination, Maintenance	19.75
23965 - Well Driller	24.56
23970 - Woodcraft Worker	23.90
23980 - Woodworker	18.49
24000 - Personal Needs Occupations	
24570 - Child Care Attendant	13.05
24580 - Child Care Center Clerk	16.03
24610 - Chore Aide	10.57
24620 - Family Readiness And Support Services Coordinator	16.03
24630 - Homemaker	19.21
25000 - Plant And System Operations Occupations	
25010 - Boiler Tender	27.59
25040 - Sewage Plant Operator	28.83
25070 - Stationary Engineer	27.59
25190 - Ventilation Equipment Tender	19.34
25210 - Water Treatment Plant Operator	28.83
27000 - Protective Service Occupations	
27004 - Alarm Monitor	23.77
27007 - Baggage Inspector	13.15
27008 - Corrections Officer	31.01
27010 - Court Security Officer	31.00
27030 - Detection Dog Handler	23.77
27040 - Detention Officer	31.01
27070 - Firefighter	29.97
27101 - Guard I	13.15
27102 - Guard II	23.77
27131 - Police Officer I	36.78
27132 - Police Officer II	40.87
28000 - Recreation Occupations	
28041 - Carnival Equipment Operator	12.76
28042 - Carnival Equipment Repairer	13.74
28043 - Carnival Equipment Worker	9.67
28210 - Gate Attendant/Gate Tender	14.16
28310 - Lifeguard	13.48
28350 - Park Attendant (Aide)	15.83
28510 - Recreation Aide/Health Facility Attendant	11.56
28515 - Recreation Specialist	19.61
28630 - Sports Official	12.61
28690 - Swimming Pool Operator	16.97
29000 - Stevedoring/Longshoremen Occupational Services	
29010 - Blocker And Bracer	23.42
29020 - Hatch Tender	23.42
29030 - Line Handler	23.42
29041 - Stevedore I	21.88
29042 - Stevedore II	24.95
30000 - Technical Occupations	
30010 - Air Traffic Control Specialist, Center (HFO) (see 2)	39.85
30011 - Air Traffic Control Specialist, Station (HFO) (see 2)	27.98
30012 - Air Traffic Control Specialist, Terminal (HFO) (see 2)	30.26
30021 - Archeological Technician I	22.52
30022 - Archeological Technician II	24.21
30023 - Archeological Technician III	34.46
30030 - Cartographic Technician	34.46

Wage Determination - LA County 2005-2047.txt

30040 - Civil Engineering Technician	30.78
30061 - Drafter/CAD Operator I	24.86
30062 - Drafter/CAD Operator II	27.81
30063 - Drafter/CAD Operator III	31.00
30064 - Drafter/CAD Operator IV	38.15
30081 - Engineering Technician I	19.68
30082 - Engineering Technician II	22.09
30083 - Engineering Technician III	24.70
30084 - Engineering Technician IV	30.60
30085 - Engineering Technician V	37.43
30086 - Engineering Technician VI	45.29
30090 - Environmental Technician	27.72
30210 - Laboratory Technician	23.13
30240 - Mathematical Technician	33.92
30361 - Paralegal/Legal Assistant I	21.83
30362 - Paralegal/Legal Assistant II	27.04
30363 - Paralegal/Legal Assistant III	33.08
30364 - Paralegal/Legal Assistant IV	40.03
30390 - Photo-Optics Technician	33.92
30461 - Technical Writer I	23.62
30462 - Technical Writer II	28.89
30463 - Technical Writer III	34.96
30491 - Unexploded Ordnance (UXO) Technician I	25.32
30492 - Unexploded Ordnance (UXO) Technician II	30.64
30493 - Unexploded Ordnance (UXO) Technician III	36.72
30494 - Unexploded (UXO) Safety Escort	25.32
30495 - Unexploded (UXO) Sweep Personnel	25.32
30620 - Weather Observer, Combined Upper Air Or (see 2)	30.42
Surface Programs	
30621 - Weather Observer, Senior (see 2)	33.79
31000 - Transportation/Mobile Equipment Operation Occupations	
31020 - Bus Aide	13.63
31030 - Bus Driver	19.62
31043 - Driver Courier	13.27
31260 - Parking and Lot Attendant	9.39
31290 - Shuttle Bus Driver	14.48
31310 - Taxi Driver	13.23
31361 - Truckdriver, Light	14.48
31362 - Truckdriver, Medium	20.63
31363 - Truckdriver, Heavy	21.78
31364 - Truckdriver, Tractor-Trailer	21.78
99000 - Miscellaneous Occupations	
99030 - Cashier	12.13
99050 - Desk Clerk	12.65
99095 - Embalmer	23.19
99251 - Laboratory Animal Caretaker I	11.02
99252 - Laboratory Animal Caretaker II	12.08
99310 - Mortician	34.35
99410 - Pest Controller	15.19
99510 - Photofinishing Worker	16.36
99710 - Recycling Laborer	21.03
99711 - Recycling Specialist	24.67
99730 - Refuse Collector	18.76
99810 - Sales Clerk	17.13
99820 - School Crossing Guard	9.51
99830 - Survey Party Chief	37.97
99831 - Surveying Aide	21.26
99832 - Surveying Technician	27.95
99840 - Vending Machine Attendant	12.77
99841 - Vending Machine Repairer	15.42
99842 - Vending Machine Repairer Helper	12.77

ALL OCCUPATIONS LISTED ABOVE RECEIVE THE FOLLOWING BENEFITS:

HEALTH & WELFARE: \$3.50 per hour or \$140.00 per week or \$606.67 per month

VACATION: 2 weeks paid vacation after 1 year of service with a contractor or successor; 3 weeks after 5 years, and 4 weeks after 15 years. Length of service includes the whole span of continuous service with the present contractor or successor, wherever employed, and with the predecessor contractors in the performance of similar work at the same Federal facility. (Reg. 29 CFR 4.173)

HOLIDAYS: A minimum of ten paid holidays per year, New Year's Day, Martin Luther King Jr's Birthday, Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans' Day, Thanksgiving Day, and Christmas Day. (A contractor may substitute for any of the named holidays another day off with pay in accordance with a plan communicated to the employees involved.) (See 29 CFR 4174)

THE OCCUPATIONS WHICH HAVE NUMBERED FOOTNOTES IN PARENTHESES RECEIVE THE FOLLOWING:

1) COMPUTER EMPLOYEES: Under the SCA at section 8(b), this wage determination does not apply to any employee who individually qualifies as a bona fide executive, administrative, or professional employee as defined in 29 C.F.R. Part 541. Because most Computer System Analysts and Computer Programmers who are compensated at a rate not less than \$27.63 (or on a salary or fee basis at a rate not less than \$455 per week) an hour would likely qualify as exempt computer professionals, (29 C.F.R. 541.400) wage rates may not be listed on this wage determination for all occupations within those job families. In addition, because this wage determination may not list a wage rate for some or all occupations within those job families if the survey data indicates that the prevailing wage rate for the occupation equals or exceeds \$27.63 per hour conformances may be necessary for certain nonexempt employees. For example, if an individual employee is nonexempt but nevertheless performs duties within the scope of one of the Computer Systems Analyst or Computer Programmer occupations for which this wage determination does not specify an SCA wage rate, then the wage rate for that employee must be conformed in accordance with the conformance procedures described in the conformance note included on this wage determination.

Additionally, because job titles vary widely and change quickly in the computer industry, job titles are not determinative of the application of the computer professional exemption. Therefore, the exemption applies only to computer employees who satisfy the compensation requirements and whose primary duty consists of:

(1) The application of systems analysis techniques and procedures, including consulting with users, to determine hardware, software or system functional specifications;

(2) The design, development, documentation, analysis, creation, testing or modification of computer systems or programs, including prototypes, based on and related to user or system design specifications;

(3) The design, documentation, testing, creation or modification of computer programs related to machine operating systems; or

(4) A combination of the aforementioned duties, the performance of which requires the same level of skills. (29 C.F.R. 541.400).

2) AIR TRAFFIC CONTROLLERS AND WEATHER OBSERVERS - NIGHT PAY & SUNDAY PAY: If you work at night as part of a regular tour of duty, you will earn a night differential and receive an additional 10% of basic pay for any hours worked between 6pm and 6am. If you are a full-time employed (40 hours a week) and Sunday is part of your regularly scheduled workweek, you are paid at your rate of basic pay plus a Sunday premium of 25% of your basic rate for each hour of Sunday work which is not overtime

Wage Determination - LA County 2005-2047.txt
(i.e. occasional work on Sunday outside the normal tour of duty is considered overtime work).

HAZARDOUS PAY DIFFERENTIAL: An 8 percent differential is applicable to employees employed in a position that represents a high degree of hazard when working with or in close proximity to ordnance, explosives, and incendiary materials. This includes work such as screening, blending, dying, mixing, and pressing of sensitive ordnance, explosives, and pyrotechnic compositions such as lead azide, black powder and photoflash powder. All dry-house activities involving propellants or explosives.

Demilitarization, modification, renovation, demolition, and maintenance operations on sensitive ordnance, explosives and incendiary materials. All operations involving regrading and cleaning of artillery ranges.

A 4 percent differential is applicable to employees employed in a position that represents a low degree of hazard when working with, or in close proximity to ordnance, (or employees possibly adjacent to) explosives and incendiary materials which involves potential injury such as laceration of hands, face, or arms of the employee engaged in the operation, irritation of the skin, minor burns and the like; minimal damage to immediate or adjacent work area or equipment being used. All operations involving, unloading, storage, and hauling of ordnance, explosive, and incendiary ordnance material other than small arms ammunition. These differentials are only applicable to work that has been specifically designated by the agency for ordnance, explosives, and incendiary material differential pay.

**** UNIFORM ALLOWANCE ****

If employees are required to wear uniforms in the performance of this contract (either by the terms of the Government contract, by the employer, by the state or local law, etc.), the cost of furnishing such uniforms and maintaining (by laundering or dry cleaning) such uniforms is an expense that may not be borne by an employee where such cost reduces the hourly rate below that required by the wage determination. The Department of Labor will accept payment in accordance with the following standards as compliance:

The contractor or subcontractor is required to furnish all employees with an adequate number of uniforms without cost or to reimburse employees for the actual cost of the uniforms. In addition, where uniform cleaning and maintenance is made the responsibility of the employee, all contractors and subcontractors subject to this wage determination shall (in the absence of a bona fide collective bargaining agreement providing for a different amount, or the furnishing of contrary affirmative proof as to the actual cost), reimburse all employees for such cleaning and maintenance at a rate of \$3.35 per week (or \$.67 cents per day). However, in those instances where the uniforms furnished are made of "wash and wear" materials, may be routinely washed and dried with other personal garments, and do not require any special treatment such as dry cleaning, daily washing, or commercial laundering in order to meet the cleanliness or appearance standards set by the terms of the Government contract, by the contractor, by law, or by the nature of the work, there is no requirement that employees be reimbursed for uniform maintenance costs.

The duties of employees under job titles listed are those described in the "Service Contract Act Directory of Occupations", Fifth Edition, April 2006, unless otherwise indicated. Copies of the Directory are available on the Internet. A link to the Directory may be found on the WHD home page at <http://www.dol.gov/esa/whd/> or through the Wage Determinations On-Line (WDOL) Web site at <http://wdol.gov/>.

REQUEST FOR AUTHORIZATION OF ADDITIONAL CLASSIFICATION AND WAGE RATE {Standard Form 1444 (SF 1444)}

Conformance Process:

Wage Determination - LA County 2005-2047.txt

The contracting officer shall require that any class of service employee which is not listed herein and which is to be employed under the contract (i.e., the work to be performed is not performed by any classification listed in the wage determination), be classified by the contractor so as to provide a reasonable relationship (i.e., appropriate level of skill comparison) between such unlisted classifications and the classifications listed in the wage determination. Such conformed classes of employees shall be paid the monetary wages and furnished the fringe benefits as are determined. Such conforming process shall be initiated by the contractor prior to the performance of contract work by such unlisted class(es) of employees. The conformed classification, wage rate, and/or fringe benefits shall be retroactive to the commencement date of the contract. {See Section 4.6 (C)(vi)} when multiple wage determinations are included in a contract, a separate SF 1444 should be prepared for each wage determination to which a class(es) is to be conformed.

The process for preparing a conformance request is as follows:

- 1) When preparing the bid, the contractor identifies the need for a conformed occupation(s) and computes a proposed rate(s).
- 2) After contract award, the contractor prepares a written report listing in order proposed classification title(s), a Federal grade equivalency (FGE) for each proposed classification(s), job description(s), and rationale for proposed wage rate(s), including information regarding the agreement or disagreement of the authorized representative of the employees involved, or where there is no authorized representative, the employees themselves. This report should be submitted to the contracting officer no later than 30 days after such unlisted class(es) of employees performs any contract work.
- 3) The contracting officer reviews the proposed action and promptly submits a report of the action, together with the agency's recommendations and pertinent information including the position of the contractor and the employees, to the Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, for review. (See section 4.6(b)(2) of Regulations 29 CFR Part 4).
- 4) Within 30 days of receipt, the Wage and Hour Division approves, modifies, or disapproves the action via transmittal to the agency contracting officer, or notifies the contracting officer that additional time will be required to process the request.
- 5) The contracting officer transmits the Wage and Hour decision to the contractor.
- 6) The contractor informs the affected employees.

Information required by the Regulations must be submitted on SF 1444 or bond paper.

When preparing a conformance request, the "Service Contract Act Directory of Occupations" (the Directory) should be used to compare job definitions to insure that duties requested are not performed by a classification already listed in the wage determination. Remember, it is not the job title, but the required tasks that determine whether a class is included in an established wage determination. Conformances may not be used to artificially split, combine, or subdivide classifications listed in the wage determination.

**ATTACHMENT F--OFFICE OF SMALL AND DISADVANTAGED BUSINESS
UTILIZATION SMALL BUSINESS SUBCONTRACTING PLAN**

**OFFICE OF SMALL AND DISADVANTAGED BUSINESS
UTILIZATION
SMALL BUSINESS SUBCONTRACTING PLAN**

The following outline meets the minimum requirements of section 8(d) of the Small Business Act, as amended, and implemented by the Federal Acquisition Regulations (FAR) Subpart 19.7. The U.S. Department of Health and Human Services (HHS), Office of Small and Disadvantaged Business Utilization (OSDBU) recommend offerors use the following format to submit proposed Individual Subcontracting Plans, including modifications. It is not intended to replace any existing Corporate/Commercial Plan that is more extensive. A subcontracting Plan is required if the estimated cost of the contract may exceed \$650,000 (\$1,500,000 for construction) Small businesses are excluded. Questions should be forwarded to the Contracting Officer or Operating Division (OPDIV) Small Business Specialist.

**HHS Operating Division (OPDIV): Health Resources and Services
Administration (HRSA)**

SOLICITATION OR CONTRACT NUMBER: 13-258-SOL-00002

DATE OF PLAN: March 11, 2013

CONTRACTOR No 1: Mediscan Diagnostic Services; **Woman-Owned**

Small Business - Occupational Therapist Services

ADDRESS: 21050 Califa St., Suite 100, Woodland Hills

STATE/ZIP CODE: California, 91367-5703

DUNN & BRADSTREET NUMBER: 147457134

ITEM/SERVICE (Description): Occupational Therapy Services provided to Hansen's Disease patients at the LAC+USC Medical Center

NEW/INITIAL CONTRACT

PERIOD OF CONTRACT PERFORMANCE: 06/01/2013 - 05/31/2014 (Base Period)

Base Period: \$54,080 Performance Period: 06/01/2013 – 05/31/2014
Quantity: 832 hours

Option 1: \$ 54,080 /Performance Period: 06/01/2014 – 05/31/2015
Quantity: 832 hours

Option 2: \$ 54,080 /Performance Period: 06/01/2015 – 05/31/2016
Quantity: 832 hours

Option 3: \$ 54,080 /Performance Period: 06/01/2016 – 05/31/2017
Quantity: 832 hours

Option 4: \$ 54,080 /Performance Period: 06/01/2017 – 05/31/2018
Quantity: 832 hours

\$ 270,400 Total Contract Cost

CONTRACTOR No. 2: Ortho Engineering, INC. – **Small Business**

ADDRESS: 1750 S. La Cienega BLVD

STATE/ZIP CODE: CA, 90035

DUNN & BRADSTREET NUMBER: 798331351

ITEM/SERVICE (Description): Orthotics and Prosthetics services provided
in the Hansen's Disease Clinic at the LAC+USC Medical Center

NEW/INITIAL CONTRACT

PERIOD OF CONTRACT PERFORMANCE: 06/01/2013 – 05/31/2014 (Base
Period)

Base Period: \$35,431 Performance Period: 06/01/2013 – 05/31/2014
Quantity: Various Orthotic and Prosthetic Devices

Option 1: \$ 35,431 /Performance Period: 06/01/2014 – 05/31/2015
Quantity: Various Orthotic and Prosthetic Devices

Option 2: \$ 35,431 /Performance Period: 06/01/2015 – 05/31/2016
Quantity: Various Orthotic and Prosthetic Devices

Option 3: \$ 35,431 /Performance Period: 06/01/2016 – 05/31/2017
Quantity: Various Orthotic and Prosthetic Devices

Option 4: \$ 35,431 /Performance Period: 06/01/2017 – 05/31/2018
Quantity: Various Orthotic and Prosthetic Devices

\$ 177,155 Total Contract Cost

CONTRACT MODIFICATION - (not applicable)

NEW PERIOD OF CONTRACT PERFORMANCE (MM/DD/YYYY -
MM/DD/YYYY): _____

Original/Base \$ _____ Performance Period/Quantity

Modification \$ _____ Performance Period/Quantity

Task Order \$ _____ Performance Period/Quantity

\$ _____ Modified Total Contract Cost

Failure to include the essential information of FAR Subpart 19.7 may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor requesting supplies or services required for performance of the contract or subcontract.

If assistance is needed to locate small business sources, contact the Small Business Specialist (SBS) supporting the OPDIV. SBS contact information is located on the OSDDBU website (<http://www.hhs.gov/about/smallbusiness/osdbustaff.html>) or you may contact the OSDDBU headquarters at (202) 690-7300.

HHS current subcontracting goal is **33.0%** for Small Business (hereafter referred to as SB), **5.00%** for Small Disadvantaged Business, including 8(a) Program Participants, Alaska Native Corporations (ANC) and Indian Tribes (hereafter referred to as SDB), **5.00%** for Women-Owned Small Business and Economically Disadvantaged Women-Owned Small Business (hereafter referred to as WOSB), **3.00%** HubZone business (hereafter referred to as HUBZone), **3.00%** Veteran Owned Small Business (hereafter referred to as VOSB) and **3.00%** Service Disabled Veteran-Owned Small Business (hereafter referred to as SDVOSB) concerns for **Fiscal Year (FY) 2012**. For this procurement, HHS expects all proposed subcontracting plans to contain at a minimum the aforementioned percentages.

These percentages shall be expressed as percentages of the total estimated subcontracting dollars.

1. Type of Plan (check one)

 X **Individual plan** (all elements developed specifically for this contract and applicable for the full term of this contract).

_____ **Master plan** (goals developed for this contract) all other elements standardized and approved by a lead agency Federal Official; must be renewed every three years and contractor must provide copy of lead agency approval.

_____ **Commercial products/service plan** (goals are negotiated with the initial agency on a company-wide basis rather than for individual contracts) this plan applies to the entire production of commercial service or items or a portion thereof. The contractor sells commercial products and services customarily used for non-government purposes. The plan is effective during the offeror's fiscal year (attach a copy). **The Summary Subcontracting Report (SSR) must include a breakout of subcontracting prorated for HHS and other Federal agencies.**

2. Goals

Below indicate the dollar and percentage goals for Small Business (SB), Small Disadvantaged (SDB) including Alaska Native Corporations and Indian Tribes, Women-owned and Economically Disadvantaged Women-Owned (WOSB), Historically Underutilized Business Zone (HUBZone), Veteran Owned Small Business (VOSB), Service-Disabled Veteran-Owned (SDVOSB) Small Businesses and "Other than Small Business" (Other) as subcontractors. Indicate the base year and each option year, as specified in FAR 19.704 or project annual subcontracting base and goals under commercial plans. If any contract has more four options, please attach additional sheets which illustrate dollar amounts and percentages. **PLEASE NOTE: Zero dollars is not an acceptable goal for the SB, SDB, WOSB, HUBZone, VOSB or SDVOSB categories since this does not demonstrate a good faith effort throughout the period of performance of the contract.** Formula for below: 2.b. + 2.h. = 2.a.

- a. **Total estimated dollar value of ALL planned subcontracting**, i.e., with ALL types of concerns under this contract is **\$480,495** (Base Period and option periods) as follows:

Base Period = \$96,099 FY 1st Option = \$96,099 FY2nd Option = \$96,099 FY 3rd Option = \$96,099 FY 4th Option = \$96,099

- b. **Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES** (including SDB, WOSB, HUBZone, VOSB and SDVOSB): (% of "a")
\$447,555 and 93.1445% (Base Period and Option periods)

Base Period: \$89,511 and 93.1445%/Performance Period: 06/01/2013 – 05/31/14

Option 1: \$89,511 and 93% /Performance Period: 06/01/2014 – 05/31/15

Option 2: \$89,511 and 93.1445%/Performance Period: 06/01/2015 – 05/31/2016
 Option 3: \$ 89,511 and 93.1445%/Performance Period: 06/01/2016 – 05/31/2017
 Option 4: \$ 89,511 and 93.1445% /Performance Period: 06/01/2017 – 05/31/18

\$ 447,555

Total Contract Cost

- c. Total estimated dollar value and percent of planned subcontracting with **SMALL BUSINESSES**: (% of "a") \$ 0 and 0 % (Base Period - If options apply)
- d. Total estimated dollar value and percent of planned subcontracting with **SMALL DISADVANTAGED BUSINESSES**: (% of "a") \$ 0 and 0 % (Base Period - If options apply)
- e. Total estimated dollar value and percent of planned subcontracting with **WOMEN-OWNED SMALL BUSINESSES (Mediscan)**: (% of "a") \$ **270,400** and 56.2752%

Base Period: \$54,080 and 56.2752% /Performance Period: 06/01/2013 – 05/31/2014

Option 1: \$ 54,080 and 56.2752% /Performance Period: 06/01/2014 – 05/31/2015

Option 2: \$ 54,080 and 56.2752% /Performance Period: 06/01/2015 – 05/31/2016

Option 3: \$ 54,080 and 56.2752%/Performance Period: 06/01/2016 – 05/31/2017

Option 4: \$ 54,080 56.2752%/Performance Period: 06/01/2017 – 05/31/2018

\$ 270,400

Total Contract Cost

- f. Total estimated dollar and percent of planned subcontracting with **HUBZone SMALL BUSINESSES**: (% of "a") \$ 0 and 0% (Base Period - If options apply)
- g. Total estimated dollar and percent of planned subcontracting with **VETERAN-OWNED SMALL BUSINESSES**: (% of "a") \$ 0 and 0% (Base Period - If options apply)
- h. Total estimated dollar and percent of planned subcontracting with **SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESSES**: (% of "a") \$ 0 and 0% (Base Period - If options apply)
- i. Total estimated dollar and percent of planned subcontracting with **"OTHER THAN SMALL BUSINESSES"** (As defined by the Small Business Administration as "any entity that is not classified as a small business. This includes large businesses, state and local governments, non-profit

organizations, public utilities, educational institutions and foreign-owned firms.) (% of "a") **\$32,940** and 6.855% (Base Period and option periods).

Base Period \$6,588 and 6.855%/Performance Period 06/01/2013 – 05/31/2014

Option 1: \$ 6,588 and 6.855%/Performance Period: 06/01/2014 – 05/31/2015

Option 2: \$ 6,588 and 6.855%/Performance Period: 06/01/2015 – 05/31/2016

Option 3: \$ 6,588 and 6.855%/Performance Period: 06/01/2016 – 05/31/2017

Option 4: \$ 6,588 and 6.855%/Performance Period: 06/01/2017 – 05/31/2018

\$32,940 Total

- j. Provide a description of ALL the products and/or services to be subcontracted under this contract, and indicate the size and type of business supplying them (check all that apply):

	Products and/or Services	Other	Small Business	SDB	WOSB	Hubz	VOSB	SDVOSB
1	Occupational Therapy Services				X			
2	Orthotic and Prosthetic Devices		X					
3	Nurse Registry Services	X						
4								
5								
6								
7								
8								
9								
10								

- k. Provide a description of the method used to develop the subcontracting goals for SB, SDB, WOSB, HUBZone and SDVOSB concerns. Address efforts made to ensure that maximum practicable subcontracting opportunities have been made available for those concerns and explain the method used to identify potential sources for solicitation purposes. Explain the method and state the quantitative basis (in dollars) used to establish the percentage goals. Also, explain

how the areas to be subcontracted to SB, WOSB, HUBZone, VOSB and SDVOSB concerns were determined, how the capabilities of these concerns were considered contract opportunities and how such data comports with the cost proposal. Identify any source lists or other resources used in the determination process. (Attach additional sheets, if necessary.)

- l. Indirect costs have___ have not x been included in the dollar and percentage subcontracting goals above (check one).
- m. If indirect costs have been included, explain the method used to determine the proportionate share of such costs to be allocated as subcontracts to SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns:

3. Program Administrator:

NAME: Mark Wycislak

TITLE: Fiscal Officer I

ADDRESS: 1100 N. State St.
Los Angeles, CA 90033

TELEPHONE: 323 226-6472

E-MAIL: mwycislak@dhs.lacounty.gov

Duties: Does the individual named above have general overall responsibility for the company's subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans and perform the following duties? **NO** (If NO is checked, please who in the company performs those duties, or indicate why the duties are not performed in your company on a separate sheet of paper and submit with the proposed subcontracting plan.)

- a. Developing and promoting company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns; and for assuring that these concerns are included on the source lists for solicitations for products and services they are capable of providing; ___yes X no
- b. Developing and maintaining bidder source lists of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns from all possible sources; ___yes X no

- c. Ensuring periodic rotation of potential subcontractors on bidder's lists;
___ yes **X** no
- d. Assuring that SB, SDB, WOSB, HUBZone, VOSB and SDVOSB businesses are included on the bidders' list for every subcontract solicitation for products and services that they are capable of providing. ___ yes **X** no
- e. Ensuring that Requests for Proposals (RFPs) are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns. ___ yes **X** no
- f. Reviewing subcontract solicitations to remove statements, clauses, etc., which might tend to restrict or prohibit small, 8(a), SDB, WOSB, HUBZone, VOSB and SDVOSB small business participation. ___ yes ___ **no**
- g. Accessing various sources for the identification of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns to include the Central Contractor Registration (<http://www.ccr.gov/>), local small business and minority associations, local chambers of commerce and Federal agencies' Small Business Offices; ___ yes **X** no
- h. Establishing and maintaining contract and subcontract award records; **X** yes ___ no
- i. Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc; ___ yes **X** no
- j. Ensuring that SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company; ___ yes **X** no
- k. Conducting or arranging for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended; ___ yes **X** no
- l. Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals; ___ yes **X** no
- m. Preparing and submitting timely, required subcontract reports; ___ **X** yes ___ no
- n. Conducting or arranging training for purchasing personnel regarding the intent and impact of 8(d) of the Small Business Act on purchasing procedures; ___ yes **X** no

- o. Coordinating the company's activities during the conduct of compliance reviews by Federal agencies; and ☐ yes ☒ no

4. Equitable Opportunity

Describe efforts the offeror will undertake to ensure that SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns will have an equitable opportunity to compete for subcontracts. These efforts include, but are not limited to, the following activities:

a. Outreach efforts to obtain sources:

1. Contact minority and small business trade associations; 2) contact business development organizations and local chambers of commerce; 3) attend SB, SDB, WOSB, HUBZone, VOSB and SDVOSB procurement conferences and trade fairs; 4) review sources from the Central Contractor Registration (<http://www.ccr.gov/>); 5) review sources from the Small Business Administration (SBA), Central Contractor Registration (CCR); 6) Consider using other sources such as the National Institutes of Health (NIH) e-Portals in Commerce, (e-PIC), (<http://epic.od.nih.gov/>). The NIH e-PIC is not a mandatory source; however, it may be used at the offeror's discretion; and 7) Utilize newspaper and magazine ads to encourage new sources.

b. Internal efforts to guide and encourage purchasing personnel:

1. Conduct workshops, seminars and training programs;
2. Establish, maintain, and utilize SB, SDB, WOSB, HUBZone, VOSB and SDVOSB source lists, guides, and other data for soliciting subcontractors; and
3. Monitor activities to evaluate compliance with the subcontracting plan.

5. Flow Down Clause

The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns," in all acquisitions exceeding the simplified acquisition threshold that offers further subcontracting opportunities. All subcontractors, except small business concerns, that

receive subcontracts in excess of \$650,000 (\$1,500,000 for construction) must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." Note: In accordance with FAR 52.212-5(e) and 52.244-6(c) the contractor is not required to include flow-down clause FAR 52.219.-9 if it is subcontracting commercial items.

6. Reporting and Cooperation .

The contractor gives assurance of 1) cooperation in any studies or surveys that may be required; 2) submission of periodic reports which illustrate compliance with the subcontracting plan; 3) submission of its Individual Subcontracting Report (ISR) and Summary Subcontract Report (SSR); and 4) subcontractors submission of ISRs and SSRs. **ISRs and SSRs shall be submitted via the Electronic Subcontracting Reporting System (eSRS) website**

<https://esrs.symplicity.com/index?tab=signin&cck=1>

Reporting Period	Report Due	Due Date
Oct 1 - Mar 31	ISR	4/30
Apr 1 - Sept 30	ISR	10/30
Oct 1 - Sept 30	SSR	10/30
Contract Completion	Year End SDB Report	30 days after completion

Please refer to FAR Part 19.7 for instruction concerning the submission of a Commercial Plan: SSR is due on 10/30 each year for the previous fiscal year ending 9/30.

- a. Submit ISR (bi-annually) for the awarding Contracting Officer's review and acceptance via the eSRS website.
- b. Currently, SSR (annually) must be submitted for the HHS eSRS Agency Coordinator review and acceptance via the eSRS website. (**Note:** Log onto the OSDBU website to view the HHS Agency Coordinator contact information (<http://www.hhs.gov/about/smallbusiness/osdbustaff.html>)).

Note: The Request for Proposal (RFP) will indicate whether a subcontracting plan is required. Due to the nature and complexity of many HHS contracts, particularly the Centers for Medicare and Medicaid (CMS), the contractor may not be required to submit its subcontracting reports through the eSRS. The Contracting Officer will confirm reporting requirements prior to the issuance of an award. For more information,

**contact Courtney Carter, Agency Coordinator-eSRS
(Courtney.Carter@hhs.gov).**

7. Record keeping

FAR 19.704(a) (11) requires a list of the types of records your company will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. The following is a recitation of the types of records the contractor will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. These records will include, but not be limited to, the following:

- a. SB, SDB, WOSB, HUBZone, VOSB and SDVOSB source lists, guides and other data identifying such vendors;
- b. Organizations contacted in an attempt to locate SB, SDB, WOSB, HUBZone, VOSB and SDVOSB sources;
- c. On a contract-by-contract basis, records on all subcontract solicitations over \$100,000, which indicate for each solicitation (1) whether SB, SDB, WOSB, HUBZone, VOSB and/or SDVOSB concerns were solicited, if not, why not and the reasons solicited concerns did not receive subcontract awards;
- d. Records to support other outreach efforts, e.g., contacts with minority and small business trade associations, attendance at small and minority business procurement conferences and trade fairs;
- e. Records to support internal guidance and encouragement provided to buyers through (1) workshops, seminars, training programs, incentive awards; and (2) monitoring performance to evaluate compliance with the program and requirements; and
- f. On a contract-by-contract basis, records to support subcontract award data including the name, address, and business type and size of each subcontractor. (This is not required on a contract-by-contract basis for commercial plans.)

8. Timely Payments to Subcontractors

FAR 19.702 requires your company to establish and use procedures to ensure the timely payment of amounts due pursuant to the terms of your subcontracts with SB concerns, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns.

Your company has established and used such procedures: x yes
 no

9. Description of Good Faith Effort

Maximum practicable utilization of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns as subcontractors in Government contracts is a matter of national interest with both social and economic benefits. **When a contractor fails to make a good faith effort to comply with a subcontracting plan, these objectives are not achieved, and 15 U.S.C. 637(d) (4) (F) directs that liquidated damages shall be paid by the contractor.** In order to demonstrate your compliance with a good faith effort to achieve the SB, SDB, WOSB, HUBZone, VOSB and SDVOSB small business subcontracting goals, outline the steps your company plans to take. These steps will be negotiated with the contracting official prior to approval of the plan.

SIGNATURE PAGE

Signatures Required:

This subcontracting plan was submitted by:

Signature: Margaret Berumen

Typed/Print Name: Margaret Berumen

Title: Chief Clinic Administrator

Date: March 11, 2013

This plan was reviewed by:

Signature: Mark Wycislak

Typed/Print Name: Mark Wycislak

Title: Contracting Officer

Date: March 11, 2013

This plan was reviewed by:

Signature: Wanda Wayne Berry

Typed/Print Name: WANDA WAYNE BERRY 5/18/13

Title: HHS Small Business Specialist Date:

This plan was reviewed by:

Signature: Mae J. Brown

Typed/Print Name:

Title: Small Business Administration Procurement Center Representative

Date: 5/18/13

This plan was approved by:

Signature: Diane Cog

Typed/Print Name: Diane Cog

Title: Contracting Officer Date: 4/30/12